

DEPARTMENT OF EDUCATION

[CFDA No. 84.025E]

Services for Children With Deaf-Blindness Program

Reopening the Closing Date for Transmittal of Applications for Technical Assistance for Transitional Services Project under the Services for Children with Deaf-Blindness Program for Fiscal Year (FY) 1992.

Purpose: On October 11, 1991, the Office of Special Education and Rehabilitative Services (OSERS) published a notice in the *Federal Register* inviting applications for new awards for FY 1992 at 56 FR 51590. The closing date was January 17, 1992 for transmittal of applications for FY 1992.

On March 24, 1992, a review panel was convened to evaluate the single application that was submitted under the competition for Services for Children with Deaf-Blindness Program, Priority 1: Technical Assistance for Transitional Services (CFDA 84.025E). The panel recommended disapproval of the

application. In order to meet the need reflected in this priority, the Secretary believes that potential applicants should be given additional time to prepare their applications and is therefore reopening the competition and announcing a new date for transmittal of applications. This notice changes the deadline date only for applications under Priority 1: Technical Assistance for Transitional Services. The applicant who submitted an application for the original deadline has the option of withdrawing its application and resubmitting a revised application, submitting amendments to its application, or leaving the original application in this competition. Any applicant wishing to apply should request a new application package.

Deadline for Transmittal of Applications: July 10, 1992.

Deadline for Intergovernmental Review: September 10, 1992.

Available Funds: \$640,000.

Estimated Range of Awards: \$640,000.

Estimated Size of Awards: \$640,000.

Estimated Number of Awards: 1.

Project Period: Up to 36 months.

Applicable Regulations: (a) The Education Department General Administrative Regulations, 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 85 and 86; (b) the regulations for this program in 34 CFR part 307, as amended and published in the *Federal Register* at 56 FR 51582-51589; and (c) the annual funding priority for this program, Technical Assistance for Transitional Services, published in the *Federal Register* at 56 FR 51586.

For Applications or Information Contact: Joseph Clair, U.S. Department of Education, 400 Maryland Avenue, S.W., Room 4622, Switzer Building, Washington, DC 20202-2734. Telephone: (202) 732-4503. Deaf and hard of hearing individual may call (202) 732-1169 for TDD services.

Program Authority: 20 U.S.C. 1422.

Dated: May 22, 1992.

Michael E. Vader,

Acting Assistant Secretary, Office of Special Education and Rehabilitative Services.

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Estimate Report

Friday
May 29, 1992

Part VI

Environmental Protection Agency

Guidelines for Exposure Assessment; Notice

ENVIRONMENTAL PROTECTION AGENCY I41[FRL-4129-5]

Guidelines for Exposure Assessment

AGENCY: U.S. Environmental Protection Agency

ACTION: Final guidelines for exposure assessment

SUMMARY: The U.S. Environmental Protection Agency (EPA) is today issuing final guidelines for exposure assessment. The Guidelines for Exposure Assessment (hereafter "Guidelines") are intended for risk assessors in EPA, and those exposure and risk assessment consultants, contractors, or other persons who perform work under Agency contract or sponsorship. In addition, publication of these Guidelines makes information on the principles, concepts, and methods used by the Agency available to all interested members of the public. These Guidelines supersede and replace both the Guidelines for Estimating Exposures published September 24, 1986 (51 FR 34042-34054) (hereafter "1986 Guidelines") and the Proposed Guidelines for Exposure-Related Measurements published for comment on December 2, 1988 (53 FR 48830-48853) (hereafter "1988 Proposed Guidelines"). In response to recommendations from the Science Advisory Board (SAB) and the public, the 1986 Guidelines were updated and combined with the 1988 Proposed Guidelines and retitled as the current Guidelines for Exposure Assessment.

These Guidelines establish a broad framework for Agency exposure assessments by describing the general concepts of exposure assessment including definitions and associated units, and by providing guidance on the planning and conducting of an exposure assessment. Guidance is also provided on presenting the results of the exposure assessment and characterizing uncertainty. Although these Guidelines focus on exposures of humans to chemical substances, much of the guidance contained herein also pertains to assessing wildlife exposure to chemicals, or to human exposures to biological, noise, or radiological agents. Since these latter four areas present unique challenges, assessments on these topics must consider additional factors beyond the scope of these Guidelines. The Agency may, at a future date, issue additional specific guidelines in these areas.

EFFECTIVE DATE: The Guidelines will be effective May 29, 1992.

FOR FURTHER INFORMATION CONTACT: Michael A. Callahan, Director, Exposure

Assessment Group, Office of Health and Environmental Assessment (RD-689), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460, 202-260-8909.

SUPPLEMENTARY INFORMATION: In its 1983 book *Risk Assessment in the Federal Government: Managing the Process*, the National Academy of Sciences recommended that Federal regulatory agencies establish "inference guidelines" to promote consistency and technical quality in risk assessment, and to ensure that the risk assessment process is maintained as a scientific effort separate from risk management. A task force within EPA accepted that recommendation and requested that Agency scientists begin to develop such guidelines.

In 1984, EPA scientists began work on risk assessment guidelines for carcinogenicity, mutagenicity, suspect developmental toxicants, chemical mixtures, and estimating exposures. Following extensive scientific and public review, these guidelines were issued on September 24, 1986 (51 FR 33992-34054). Subsequent work resulted in the publishing of four additional proposals (one of which has recently become final): Proposed Guidelines for Assessing Female Reproductive Risk (53 FR 24834-24847), Proposed Guidelines for Assessing Male Reproductive Risk (53 FR 24850-24869), Proposed Guidelines for Exposure-Related Measurements (53 FR 48830-48853), and Proposed Amendments to the Guidelines for the Health Assessment of Suspect Developmental Toxicants (54 FR 9386-9403). The final Guidelines for Developmental Toxicity Risk Assessment, published December 5, 1991 (56 FR 63798-63826), supersede and replace the proposed amendments.

The Guidelines issued today continue the guidelines development process initiated in 1984. Like the guidelines issued in 1986, the Guidelines issued today set forth principles and procedures to guide EPA scientists in the conduct of Agency risk assessments and to inform Agency decision makers and the public about these procedures. In particular, the Guidelines standardize terminology used by the Agency in exposure assessment and in many areas outline the limits of sound scientific practice. They emphasize that exposure assessments done as part of a risk assessment need to consider the hazard identification and dose-response parts of the risk assessment in the planning stages of the exposure assessment so that these three parts can be smoothly integrated into the risk characterization. The Guidelines discuss and reference a

number of approaches and tools for exposure assessment, along with discussion of their appropriate use. The Guidelines also stress that exposure estimates along with supporting information will be fully presented in Agency risk assessment documents, and that Agency scientists will identify the strengths and weaknesses of each assessment by describing uncertainties, assumptions, and limitations, as well as the scientific basis and rationale for each assessment.

Work on these Guidelines began soon after publication of the 1986 Guidelines. At that time, the SAB recommended that the Agency develop supplementary guidelines for conducting exposure studies. This supplementary guidance was developed by an Agency work group composed of scientists from throughout the Agency, a draft was peer reviewed by experienced professionals from environmental groups, industry, academia, and other governmental agencies, and proposed for comment on December 2, 1988 (as Proposed Guidelines for Exposure-Related Measurements). In the public notice, the Agency asked for comment on whether the proposed guidelines should be combined with the 1986 guidelines in order to have a single Agency guideline for exposure assessment. Comments from the public and the SAB were heavily in favor of combining the two guidelines.

Since proposal, the Agency has reformatted the 1988 Proposed Guidelines to allow incorporation of the information in the 1986 Guidelines, and incorporated revisions resulting from additional public and SAB comments, to establish the current Guidelines. The current Guidelines were reviewed by the Risk Assessment Forum and the Risk Assessment Council, subjected to an external peer review, and presented to the SAB on September 12, 1991 for final comment (EPA-SAB-IAQC-92-015). In addition, the Guidelines were reviewed by the Working Party on Exposure Assessment, an interagency working group under the Subcommittee on Risk Assessment of the Federal Coordinating Committee on Science, Engineering and Technology. Comments of these groups have been considered in the revision of these Guidelines. The full text of the final Guidelines for Exposure Assessment is published here.

These Guidelines were developed as part of an interoffice guidelines development program under the auspices of the Risk Assessment Forum and the Office of Health and Environmental Assessment in the Agency's Office of Research and

Development. The Agency is continuing to study risk assessment issues raised in these Guidelines, and will revise them in line with new information as appropriate.

Following this preamble are two parts: Part A is the Guidelines and Part B is the Response to the Public and Science Advisory Board comments submitted in response to the 1988 Proposed Guidelines.

References, supporting documents, and comments received on the 1988 Proposed Guidelines, as well as a copy of these final Guidelines for Exposure Assessment are available for inspection at the ORD Public Information Shelf, EPA Headquarters Library (202-260-5926), 401 M Street, SW., Washington, DC, between the hours of 8 a.m. and 4:30 p.m.

Dated: April 28, 1992.

William K. Reilly,
Administrator.

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Abbreviations and Acronyms

- ADD—Average daily dose
 AF—Absorption fraction
 AT—Averaging time
 BW—Body weight
 C—Exposure concentration
 C(t)—Exposure concentration as a function of time
 CO—Carbon monoxide
 CT—Contact time
 D—Dose
 D_{app}—Applied dose
 D_{int}—Internal dose
 D_{pot}—Potential dose
 DQO—Data quality objective
 E—Exposure
 ED—Exposure duration
 EPA—U.S. Environmental Protection Agency
 F_{adh}—Adherence factor for soil
 f(t)—Absorption function
 IR—Intake rate (also ingestion or inhalation rate)
 J—Flux
 K_p—Permeability coefficient

LADD—Lifetime average daily dose
 LOAEL—Lowest observable adverse effect level
 LOD—Limit of detection
 LT—Lifetime
 M_{medium}—Amount (mass) of carrier medium material applied to the skin
 MDL—Method detection limit
 MEI—Maximally exposed individual or most exposed individual
 ND—Not detected
 PMN—Premanufacture notice
 QA—Quality assurance
 QAPP—Quality assurance project plan
 QC—Quality control
 QL—Quantification limit
 RfC—Reference concentration
 RfD—Reference dose
 SA—Surface area
 SAB—Science Advisory Board
 TEAM—Total exposure assessment methodology
 TUBE—Theoretical upper bounding estimate
 UCL—Upper confidence limit (often used to refer to the upper confidence limit of the mean)
 UR—Uptake rate

Part A: Guidelines for Exposure Assessment

1. Introduction

In 1984, the U. S. Environmental Protection Agency (EPA) initiated a program to ensure scientific quality and technical consistency of Agency risk assessments. One of the goals of the program was to develop risk assessment guidelines that would be used Agencywide. The guidelines development process includes a public review and comment period for all proposed guidelines as well as Agency Science Advisory Board review. Following the review process, the guidelines are revised if needed and then issued as final guidelines. The Guidelines for Estimating Exposures (hereafter "1986 Guidelines") were one of five guidelines issued as final in 1986 (U.S. EPA, 1986a). In 1988, the Proposed Guidelines for Exposure-Related Measurements (hereafter "1988 Proposed Guidelines") were published in the Federal Register for public review and comment (U.S. EPA, 1988a). The 1988 Proposed Guidelines were intended to be a companion and supplement to the 1986 Guidelines.

When proposing the 1988 guidelines, the Agency asked both the EPA Science Advisory Board (SAB) and the public for comments on combining the 1986 and 1988 exposure guidelines into a larger, more comprehensive guideline; the majority of comments received were in favor of doing so. Thus, these 1992 Guidelines for Exposure Assessment (hereafter "Guidelines") combine, reformat, and substantially update the earlier guidelines. These guidelines make use of developments in the

exposure assessment field since 1988, both revising the previous work and adding several topics not covered in the 1986 or 1988 guidelines. Therefore, the 1992 guidelines are being issued by the Agency as a replacement for both the 1986 Guidelines and the 1988 Proposed Guidelines.

1.1. Intended Audience

This document is intended for exposure and risk assessors in the Agency and those exposure and risk assessment consultants, contractors, or other persons who perform work under Agency contract or sponsorship. Risk managers in the Agency may also benefit from this document since it clarifies the terminology and methods used by assessors, which in some cases could strengthen the basis for decisions. In addition, publication of these guidelines makes information on the principles, concepts, and methods used by the Agency available to other agencies, States, industry, academia, and all interested members of the public.

1.2. Purpose and Scope of the Guidelines

There are a number of different purposes for exposure assessments, including their use in risk assessments, status and trends analysis, and epidemiology. These Guidelines are intended to convey the general principles of exposure assessment, not to serve as a detailed instructional guide. The technical documents cited here provide more specific information for individual exposure assessment situations. As the Agency performs more exposure assessments and incorporates new approaches, these Guidelines will be revised.

Agency risk assessors should use these Guidelines in conjunction with published guidelines for assessing health effects such as cancer (U.S. EPA, 1986b), developmental toxicity (U.S. EPA, 1991a), mutagenic effects (U.S. EPA, 1986c), and reproductive effects (U.S. EPA, 1988b; U.S. EPA, 1988c). These exposure assessment guidelines focus on human exposure to chemical substances. Much of the guidance contained herein also applies to wildlife exposure to chemicals, or human exposure to biological, physical (i.e., noise), or radiological agents. Since these areas present unique challenges, however, assessments on these topics must consider additional factors beyond the scope of these Guidelines.

For example, ecological exposure and risk assessment may deal with many species which are interconnected via complex food webs, while these guidelines deal with one species,

humans. While these guidelines discuss human exposure on the individual and population levels, ecological exposure and risk assessments may need to address community, ecosystem, and landscape levels, also. Whereas chemical agents may degrade or be transformed in the environment, biological agents may of course grow and multiply, an area not covered in these guidelines. The Agency may, at a future date, issue specific guidelines in these areas.

Persons subject to these Guidelines should use the terms associated with chemical exposure assessment in a manner consistent with the glossary in Section 8. Throughout the public comment and SAB review process, the Agency has sought definitions that have consensus within the scientific community, especially those definitions common to several scientific fields. The Agency is aware that certain well understood and widely accepted concepts and definitions in the area of health physics (such as the definition of exposure) differ from the definitions in this glossary. The definitions in this glossary are not meant to replace such basic definitions used in another field of science. It was not possible, however, to reconcile all the definitions used in various fields of science, and the ones used in the glossary are thought to be the most appropriate for the field of chemical exposure assessment.

The Agency may, from time to time, issue updates of or revisions to these Guidelines.

1.3. Organization of the Guidelines

These Guidelines are arranged in an order that assessors commonly use in preparing exposure assessments. Section 2 deals with general concepts, section 3 with planning, section 4 with data development, section 5 with calculating exposures, section 6 with uncertainty evaluation, and section 7 with presenting the results. In addition, these Guidelines include a glossary of terms (section 8) and references to other documents (section 9).

2. General Concepts in Exposure Assessment

Exposure assessment in various forms dates back at least to the early twentieth century, and perhaps before, particularly in the fields of epidemiology (World Health Organization [WHO], 1983), industrial hygiene (Cook, 1969; Paustenbach, 1985), and health physics (Upton, 1988). Epidemiology is the study of disease occurrence and the causes of disease, while the latter fields deal primarily with occupational exposure.

Exposure assessment combines elements of all three disciplines. This has become increasingly important since the early 1970s due to greater public, academic, industrial, and governmental awareness of chemical pollution problems.

Because there is no agreed-upon definition of the point on or in the body where exposure takes place, the terminology used in the current exposure assessment literature is inconsistent. Although there is reasonable agreement that human exposure means contact with the chemical or agent (Allaby, 1983; Environ Corporation, 1988; Hodgson *et al.*, 1988; U.S. EPA, 1986a), there has not yet been widespread agreement as to whether this means contact with (a) the visible exterior of the person (skin and openings into the body such as mouth and nostrils), or (b) the so-called exchange boundaries where absorption takes place (skin, lung, gastrointestinal tract).¹ These different definitions have led to some ambiguity in the use of terms and units for quantifying exposure.²

Comments on the 1986 Guidelines and the 1988 Proposed Guidelines suggested that EPA examine how exposure and dose were defined in Agency assessments and include guidance on appropriate definitions and units. After internal discussions and external peer review, it is the Agency's position that defining exposure as taking place at the visible external boundary, as in (a) above, is less ambiguous and more consistent with nomenclature in other scientific fields. This is a change from the 1986 Guidelines.

Under this definition, it is helpful to think of the human body as having a hypothetical outer boundary separating inside the body from outside the body. This outer boundary of the body is the skin and the openings into the body such as the mouth, the nostrils, and punctures and lesions in the skin. As used in these Guidelines, exposure to a chemical is the contact of that chemical with the outer boundary. An exposure assessment is the quantitative or

qualitative evaluation of that contact; it describes the intensity, frequency, and duration of contact, and often evaluates the rates at which the chemical crosses the boundary (chemical intake or uptake rates), the route by which it crosses the boundary (exposure route; e.g., dermal, oral, or respiratory), and the resulting amount of the chemical that actually crosses the boundary (a dose) and the amount absorbed (internal dose).

Depending on the purpose for which an exposure assessment will be used, the numerical output of an exposure assessment may be an estimate of either exposure or dose. If exposure assessments are being done as part of a risk assessment that uses a dose-response relationship, the output usually includes an estimate of dose.³ Other risk assessments, for example many of those done as part of epidemiologic studies, use empirically derived exposure-response relationships, and may characterize risk without the intermediate step of estimating dose.

2.1. Concepts of Exposure, Intake, Uptake, and Dose

The process of a chemical entering the body can be described in two steps: contact (exposure), followed by actual entry (crossing the boundary). Absorption, either upon crossing the boundary or subsequently, leads to the availability of an amount of the chemical to biologically significant sites within the body (internal dose⁴). Although the description of contact with the outer boundary is simple conceptually, the description of a chemical crossing this boundary is somewhat more complex.

There are two major processes by which a chemical can cross the boundary from outside to inside the body. Intake involves physically moving the chemical in question through an opening in the outer boundary (usually the mouth or nose), typically via inhalation, eating, or drinking. Normally the chemical is contained in a medium

such as air, food, or water; the estimate of how much of the chemical enters into the body focuses on how much of the carrier medium enters. In this process, mass transfer occurs by bulk flow, and the amount of the chemical itself crossing the boundary can be described as a chemical intake rate. The chemical intake rate is the amount of chemical crossing the outer boundary per unit time, and is the product of the exposure concentration times the ingestion or inhalation rate. Ingestion and inhalation rates are the amount of the carrier medium crossing the boundary per unit time, such as m³ air breathed/hour, kg food ingested/day, or liters of water consumed/day. Ingestion or inhalation rates typically are not constant over time, but often can be observed to vary within known limits.⁵

The second process by which a chemical can cross the boundary from outside to inside the body is uptake. Uptake involves absorption of the chemical through the skin or other exposed tissue such as the eye. Although the chemical is often contained in a carrier medium, the medium itself typically is not absorbed at the same rate as the chemical, so estimates of the amount of the chemical crossing the boundary cannot be made in the same way as for intake (see section 2.1.3.). Dermal absorption is an example of direct uptake across the outer boundary of the body.⁶ A chemical uptake rate is the amount of chemical absorbed per unit time. In this process, mass transfer occurs by diffusion, so uptake can depend on the concentration gradient across the boundary, permeability of the barrier, and other factors. Chemical uptake rates can be expressed as a function of the exposure concentration, permeability coefficient, and surface area exposed, or as a flux (see section 2.1.4.).

The conceptual process of contact, then entry and absorption, can be used to derive the equations for exposure and dose for all routes of exposure.

2.1.1. Exposure

The condition of a chemical contacting the outer boundary of a human is exposure. Most of the time, the chemical is contained in air, water, soil, a product, or a transport or carrier medium; the chemical concentration at the point of contact is the exposure

¹ A third, less common, scheme is that exposure is contact with any boundary outside or inside of the body, including internal boundaries around organs, etc. This scheme is alluded to, for example, in an article prepared by the National Research Council (NRC, 1985, p. 91). One could then speak of exposure to the whole person or exposure to certain internal organs.

² For example, the amount of food ingested would be a dose under scheme (a) and an exposure under scheme (b). Since the amount ingested in an animal toxicology study is usually termed administered dose, this leads to the use of both exposure and dose for the same quantity under scheme (b). There are several such ambiguities in any of the currently used schemes. Brown (1987) provides a discussion of various units used to describe exposures due to multiple schemes.

³ The National Research Council's 1983 report *Risk Assessment in the Federal Government: Managing the Process* often addresses the output of an exposure assessment as an exposure or a dose (NRC 1983, pp. 32, 35-38).

⁴ These guidelines use the term internal dose to refer to the amount of a chemical absorbed across the exchange boundaries, such as the skin, lung, or gastrointestinal tract. The term absorbed dose is often used synonymously for internal dose, although the connotation for the term absorbed dose seems to be more related to a specific boundary (the amount absorbed across a membrane in an experiment, for example), while the term internal dose seems to connote a more general sense of the amount absorbed across one or more specific sites. For the purpose of these guidelines, the term internal dose is used for both connotations. The term internal dose as used here is also consistent with how it is generally applied to a discussion of biomarkers (NRC, 1989a). It is also one of the terms used in epidemiology (NRC, 1985).

⁵ Ingestion of food or water is an intermittent rather than continuous process, and can be expressed as (amount of medium per event) \times (events per unit clock or calendar time) [the frequency of contact]; (e.g., 250 mL of water/glass of water ingested \times 8 glasses of water ingested/day).

⁶ Uptake through the lung, gastrointestinal tract, or other internal barriers also can occur following intake through ingestion or inhalation.

concentration. Exposure over a period of time can be represented by a time-dependent profile of the exposure concentration. The area under the curve of this profile is the magnitude of the exposure, in concentration-time units (Lioy, 1990; NRC, 1990):

$$E = \int_{t_1}^{t_2} C(t) dt \quad (2-1)$$

where E is the magnitude of exposure, C(t) is the exposure concentration as a function of time, and t is time, $t_2 - t_1$ being the exposure duration (ED). If ED is a continuous period of time (e.g., a day, week, year, etc.), then C(t) may be zero during part of this time. ⁷ Integrated exposures are done typically for a single individual, a specific chemical, and a particular pathway or exposure route over a given time period. ⁸

The integrated exposures for a number of different individuals (a population or population segment, for example), may then be displayed in a histogram or curve (usually, with integrated exposure increasing along the abscissa or x-axis, and the number of individuals at that integrated exposure increasing along the ordinate or y-axis). This histogram or curve is a presentation of an exposure distribution for that population or population segment. The utility of both individual exposure profiles and population exposure distributions is discussed in Section 2.3.

2.1.2. Applied Dose and Potential Dose

Applied dose is the amount of a chemical at the absorption barrier (skin, lung, gastrointestinal tract) available for absorption. It is useful to know the applied dose if a relationship can be established between applied dose and internal dose, a relationship that can sometimes be established experimentally. Usually, it is very difficult to measure the applied dose directly, as many of the absorption barriers are internal to the human and are not localized in such a way to make measurement easy. An approximation of applied dose can be made, however,

using the concept of potential dose⁹ (Lioy, 1990; NRC, 1990).

Potential dose is simply the amount of the chemical ingested, inhaled, or in material applied to the skin. It is a useful term or concept for those instances in which there is exposure to a discrete amount of chemical or transport medium, such as eating a certain amount of food or applying a certain amount of material to the skin. ¹⁰

The potential dose for ingestion and inhalation is analogous to the administered dose in a dose-response experiment. Human exposure to environmental chemicals is generally inadvertent rather than administered, so in these Guidelines it is termed potential dose rather than administered dose. Potential dose can be used for dose-response relationships based on administered dose.

For the dermal route, potential dose is the amount of chemical applied, or the amount of chemical in the medium applied, for example as a small amount of particulate deposited on the skin. Note that as all of the chemical in the particulate is not contacting the skin, this differs from exposure (the concentration in the particulate times the time of contact) and applied dose (the amount in the layer actually touching the skin).

The applied dose, or the amount that reaches the exchange boundaries of the skin, lung, or gastrointestinal tract, may often be less than the potential dose if the material is only partly bioavailable. Where data on bioavailability are known, adjustments to the potential dose to convert it to applied dose and internal dose may be made. ¹¹

⁹ Potential dose is the potential amount of the chemical that could be absorbed if it were 100% bioavailable. Note, however, that this does not imply that 100% bioavailability or 100% absorption is assumed when using potential dose. The equations and discussion in this chapter use potential dose as a measurable quantity that can then be converted to applied or absorbed dose by the use of the appropriate factors. Potential dose is a general term referring to any of the exposure routes. The terms respiratory dose, oral dose, or dermal dose are sometimes used to refer to the route-specific potential doses.

¹⁰ It is not useful to calculate potential doses in cases where there is partial or total immersion in a fluid such as air or water. In these cases, it is more useful to describe the situation in terms of exposure (concentration of the chemical in the medium times the time of contact) or absorbed dose. For cases such as contact with water in a swimming pool, the person is not really exposed to the entire mass of the chemical that would be described by a potential dose. Nor is it useful to calculate dermal applied doses because the boundary layer is being constantly renewed. The use of alternate ways to calculate a dose that might occur while swimming is discussed in Section 2.1.4.2., in conjunction with Equations 2-7 and 2-8.

¹¹ This may be done by adding a bioavailability factor (range: 0 to 1) to the dose equation. The bioavailability factor would then take into account

2.1.3. Internal Dose

The amount of a chemical that has been absorbed and is available for interaction with biologically significant receptors is called the internal dose. Once absorbed, the chemical can undergo metabolism, storage, excretion, or transport within the body. The amount transported to an individual organ, tissue, or fluid of interest is termed the delivered dose. The delivered dose may be only a small part of the total internal dose. The biologically effective dose, or the amount that actually reaches cells, sites, or membranes where adverse effects occur (NRC, 1990, p. 29), may only be a part of the delivered dose, but it is obviously the crucial part. Currently, most risk assessments dealing with environmental chemicals (as opposed to pharmaceutical assessments) use dose-response relationships based on potential (administered) dose or internal dose, since the pharmacokinetics necessary to base relationships on the delivered dose or biologically effective doses are not available for most chemicals. This may change in the future, as more becomes known about the pharmacokinetics of environmental chemicals.

Doses are often presented as dose rates, or the amount of a chemical dose (applied or internal) per unit time (e.g., mg/day), or as dose rates on a per-unit-body-weight basis (e.g., mg/kg/day).

Distributions of individual doses within a population or population segment may be displayed in a histogram or curve analogous to the exposure distributions described in section 2.1.1. The utility of individual dose profiles, as well as the utility of population distributions of dose are described more fully in section 2.3.

2.1.4. Exposure and Dose Relationships

Depending on the use of the exposure assessment, estimates of exposure and dose in various forms may be required.

- Exposure concentrations are useful when comparing peak exposures to levels of concern such as short-term exposure limits (STELs). They are typically expressed in units such as $\mu\text{g}/\text{m}^3$, mg/m^3 , mg/kg , $\mu\text{g}/\text{L}$, mg/L , ppb, or ppm.

- Exposure or dose profiles describe the exposure concentration or dose as a function of time. Concentration and time are used to depict exposure, while amount and time characterize dose;

the ability of the chemical to be extracted from the matrix, absorption through the exchange boundary, and any other losses between ingestion and contact with the lung or gastrointestinal tract. When no data or information are available to indicate otherwise, the bioavailability factor is usually assumed to be 1.

⁷ Contact time (CT) is that part of the exposure duration where C(t) does not equal zero; that is, the actual time periods (events, episodes) during which actual exposure is taking place. The exposure duration as defined here, on the other hand, is a time interval of interest for assessment purposes during which exposure occurs, either continuously or intermittently.

⁸ An exposure pathway is the course a chemical takes from its source to the person being contacted. An exposure route is the particular means of entry into the body, e.g., inhalation, ingestion, or dermal absorption.

graphical or tabular presentations may be used for either type of profile.

Such profiles are very important for use in risk assessment where the severity of effect is dependent on the pattern by which the exposure occurs rather than the total (integrated) exposure. For example, a developmental toxin may only produce effects if exposure occurs during a particular stage of development. Similarly, a single acute exposure to very high contaminant levels may induce adverse effects even if the average exposure is much lower than apparent no-effect levels. Such profiles will become increasingly important as biologically based dose-response models become available.

- Integrated exposures are useful when a total exposure for a particular route (i.e., the total for various pathways leading to exposure via the same route) is needed. Units of integrated exposure are concentration times time. The integrated exposure is the total area under the curve of the exposure profile (Equation 2-1). Note that an exposure profile (a picture of exposure concentration over time) contains more information than an integrated exposure (a number), including the duration and periodicity of exposure, the peak exposure, and the shape of the area under the time-concentration curve.

- Time-weighted averages are widely used in exposure assessments, especially as part of a carcinogen risk assessment. A time-weighted average exposure concentration (units of

concentration) is the integrated exposure divided by the period where exposure occurs, and is useful in some of the equations discussed below in estimating dose. A time-weighted average dose rate is the total dose divided by the time period of dosing, usually expressed in units of mass per unit time, or mass/time normalized to body weight (e.g., mg/kg/day). Time-weighted average dose rates such as the lifetime average daily dose (LADD) are often used in dose-response equations to estimate effects or risk.¹²

The discussion in the next three sections focuses on exposure via inhalation, oral intake, and dermal absorption. Other exposure routes are possible, however, including direct introduction into the bloodstream via injection or transfusion, contamination of exposed lesions, placental transfer, or use of suppositories. The exposures and doses for these routes can be calculated

¹² Current carcinogen risk models, such as the linearized multistage procedure and other linear nonthreshold models, use lifetime exposures to develop the dose-response relationships, and therefore use lifetime time-weighted average exposures to estimate risks. Within the range of linearity for risk, this procedure effectively treats exposures and doses as a series of "units," with each unit of dose being equal to any other unit of dose in terms of risk potential without respect to prior exposure or dose patterns. Current research in the field of dose-response modeling is focusing on biologically based dose-response models which may take into account the effects of the exposure or dose patterns, making use of all of the information in an exposure or dose profile. For a more indepth discussion on the implications of the use of time-weighted averages, see Atherley (1985).

in a similar manner, depending on whether an intake or uptake process is involved.

Although equations for calculating exposure, dose, and their various averages are in widespread use in exposure assessment, the assessor should consider the implications of the assumptions used to derive the equations. Simplifying assumptions used in deriving the equations may mean that variations in exposure concentration, ingestion or inhalation rate, permeability coefficient, surface area exposed, and absorption fraction can introduce error into the estimate of dose if average values are used, and this must be considered in the evaluation of uncertainty (section 6).

2.1.4.1. Calculating Potential Dose for Intake Processes

The general equation for potential dose for intake processes, e.g., inhalation and ingestion (see Figure 2-1 for illustration of various exposures and doses) is simply the integration of the chemical intake rate (concentration of the chemical in the medium times the intake rate of the medium, C times IR) over time:

$$D_{\text{pot}} = \int_{t_1}^{t_2} C(t) IR(t) dt \quad (2-2)$$

where D_{pot} is potential dose and $IR(t)$ is the ingestion or inhalation rate.

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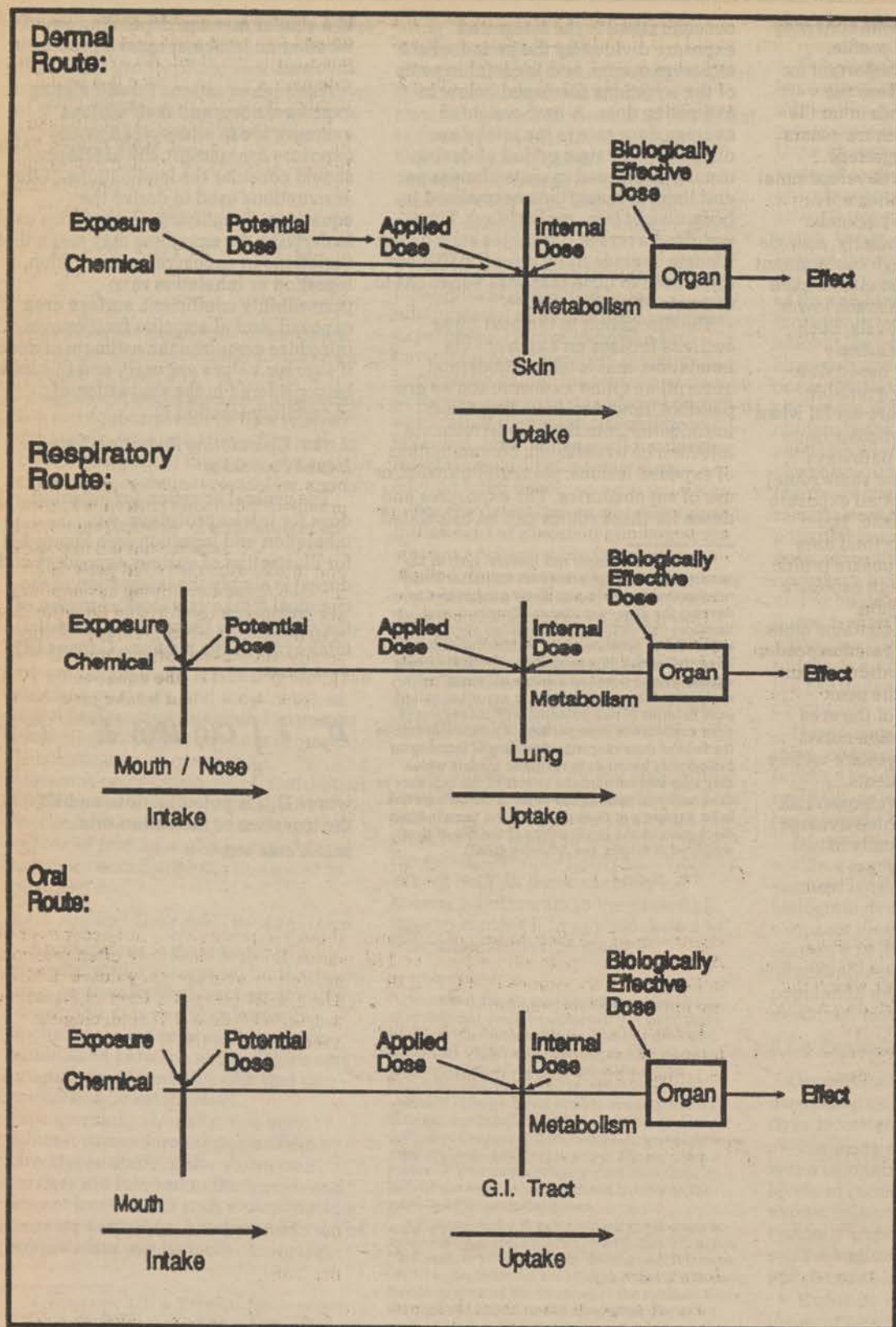


Figure 2-1. Schematic of dose and exposure.

The quantity $t_2 - t_1$, as before, represents the period of time over which exposure is being examined, or the exposure duration (ED). The exposure duration may contain times where the chemical is in contact with the person, and also times when $C(t)$ is zero. Contact time represents the actual time period where the chemical is in contact with the person. For cases such as ingestion, where actual contact with food or water is intermittent, and consequently the actual contact time may be small, the intake rate is usually expressed in terms of a frequency of events (e.g., 8 glasses of water consumed per day) times the intake per event (e.g., 250 mL of water/glass of water consumed). Intermittent air exposures (e.g., 8 hours exposed/day times one cubic meter of air inhaled/hour) can also be expressed easily using exposure duration rather than contact time. Hereafter, the term exposure duration will be used in the examples below to refer to the term $t_2 - t_1$, since it occurs frequently in exposure assessments and it is often easier to use.

Equation 2-2 can also be expressed in discrete form as a summation of the doses received during various events i:

$$D_{pot} = \sum_i C_i \cdot IR_i \cdot ED_i \quad (2-3)$$

where ED_i is the exposure duration for event i. If C and IR are nearly constant (which is a good approximation if the contact time is very short), Equation 2-3 becomes:

$$D_{pot} = \bar{C} \cdot \bar{IR} \cdot ED \quad (2-4)$$

where ED is the sum of the exposure durations for all events, and \bar{C} and \bar{IR} are the average values for these parameters. Equation 2-4 will not necessarily hold in cases where C and IR vary considerably. In those cases, Equation 2-3 can be used if the exposure can be broken out into segments where C and IR are approximately constant. If even this condition cannot be met, Equation 2-2 may be used.

For risk assessment purposes, estimates of dose should be expressed in a manner that can be compared with available dose-response data. Frequently, dose-response relationships are based on potential dose (called administered dose in animal studies), although dose-response relationships are sometimes based on internal dose.

Doses may be expressed in several different ways. Solving Equations 2-2, 2-3, or 2-4, for example, gives a total dose accumulated over the time in question. The dose per unit time is the dose rate, which has units of mass/time

(e.g., mg/day). Because intake and uptake can vary, dose rate is not necessarily constant. An average dose rate over a period of time is a useful number for many risk assessments.

Exposure assessments should take into account the time scale related to the biological response studied unless the assessment is intended to provide data on the range of biological responses (NRC, 1990, p. 28). For many noncancer effects, risk assessments consider the period of time over which the exposure occurred, and often, if there are no excursions in exposure that would lead to acute effects, average exposures or doses over the period of exposure are sufficient for the assessment. These averages are often in the form of average daily doses (ADDs).

An ADD can be calculated from Equation 2-2 by averaging D_{pot} over body weight and an averaging time, provided the dosing pattern is known so the integral can be solved. It is unusual to have such data for human exposure and intake over extended periods of time, so some simplifying assumptions are commonly used. Using Equation 2-4 instead of 2-2 or 2-3 involves making steady-state assumptions about C and IR , but this makes the equation for ADD easier to solve.¹³ For intake processes, then, using Equation 2-4, this becomes:

$$ADD_{pot} = [\bar{C} \cdot \bar{IR} \cdot ED] / [BW \cdot AT] \quad (2-5)$$

where ADD_{pot} is the average daily potential dose, BW is body weight, and AT is the time period over which the dose is averaged (converted to days). As with Equation 2-4, the exposure concentration \bar{C} is best expressed as an estimate of the arithmetic mean

regardless of the distribution of the data. Again, using average values for C and IR in Equation 2-5 assumes that C and IR are approximately constant.

For effects such as cancer, where the biological response is usually described in terms of lifetime probabilities, even

though exposure does not occur over the entire lifetime, doses are often presented as lifetime average daily doses (LADDs). The LADD takes the form of Equation 2-5, with lifetime (LT) replacing the averaging time (AT):

$$ADD_{pot} = [\bar{C} \cdot \bar{IR} \cdot ED] / [BW \cdot LT] \quad (2-6)$$

The LADD is a very common term used in carcinogen risk assessment where linear nonthreshold models are employed.

2.1.4.2. Calculating Internal Dose for Uptake Processes (Especially via the Dermal Route)

For absorption processes, there are two methods generally in use for calculating internal dose. The first, commonly used for dermal absorption from a liquid where at least partial immersion occurs, is derived from the equation for internal dose, D_{int} , which is analogous to Equation 2-2 except that

the chemical uptake rate ($C \cdot K_p \cdot SA$) replaces the chemical intake rate ($C \cdot IR$). Thus,

$$D_{int} = \int_{t_1}^{t_2} C(t) \cdot K_p \cdot SA(t) dt \quad (2-7)$$

¹³ The assessor should keep in mind that this steady state assumption has been made when using Equation 2-5, and should be able to discuss what effect using average values for C , IR , and ED has on the resulting estimate.

where K_p is the permeability coefficient, and SA is the surface area exposed. Both C and SA will vary over time, and although K_p may not vary over time, it may vary over different parts of the body. Unlike the intake processes, where the rate of the carrier medium crossing the boundary can be observed or measured, the carrier may or may not cross the absorption barrier; the equations must be in terms of the

chemical itself crossing. The flow of the chemical across the barrier (or flux, J) is not directly measurable, and is dependent on many factors including the nature of the chemical, the nature of the barrier, active transport versus passive diffusion processes, and the concentration of the chemical contacting the barrier. The relationship between the flux and the exposure concentration¹⁴ is usually expressed as a permeability coefficient, K_p , which is

experimentally measurable.¹⁵ The internal dose that is analogous to the potential dose in Equation 2-4 would be:

$$D_{int} = \bar{C} \cdot K_p \cdot \bar{SA} \cdot ED \quad (2-8)$$

where \bar{SA} is the average surface area exposed and the ADD_{int} (average daily internal dose) becomes:

$$ADD_{int} = [\bar{C} \cdot K_p \cdot \bar{SA} \cdot ED] / [BW \cdot AT] \quad (2-9)$$

(The corresponding $LADD_{int}$ would be obtained by substituting LT for AT.) This is the method to use when calculating internal dose for a swimmer. The total body surface area (SA) is assumed to be exposed to a layer of water with an average chemical concentration \bar{C} for a period of time (ED). It is not necessary to know the mass of the chemical that comes in contact with the skin. The assumptions necessary in going from Equation 2-7 to Equation 2-9 are comparable to those

made in deriving Equation 2-5. Recall that both C and SA will vary over time, and K_p may not be constant over different parts of the body. If the assumption used to derive Equation 2-5 (that these variables are nearly constant) does not hold, a different form of the equation having several terms must be used.

The second method of calculating internal dose uses empirical observations or estimates of the rate that a chemical is absorbed when a dose

is administered or applied. It is useful when a small or known amount of material (such as a particulate) or a chemical (such as a pesticide) contacts the skin. The potential dose of a chemical to the skin, D_{pot} , can often be calculated from knowing the concentration (C) and the amount of carrier medium applied (M_{medium}), either as a whole or on a unit surface area basis. For example, potential dose from dermal contact with soil can be calculated using the following equation:

$$D_{pot} = \bar{C} \cdot M_{medium} = \bar{C} \cdot F_{adh} \cdot \bar{SA} \cdot ED \quad (2-10)$$

where D_{pot} is potential dose, M_{medium} is amount of soil applied, and F_{adh} is the adherence factor for soil (the amount of soil applied to and adhering to the skin on a unit surface area per unit time).

The relationship between potential dose and applied dose for dermal exposures is that potential dose includes the amount of the chemical in the total amount of medium contacting the skin, e.g., the amount of chemical in the soil whether or not all the chemical itself ever comes in direct contact, and applied dose includes only that amount of the chemical which actually directly

touches the skin. Theoretically, the relationship between the applied dose (D_{app}) and the internal (or absorbed) dose (D_{int}) can be thought of as:

$$D_{int} = D_{app} \int_{t_1}^{t_2} f(t) dt \quad (2-11)$$

where $f(t)$ is a complicated nonlinear absorption function, usually not measurable, having the dimensions of mass absorbed per mass applied per unit time. The absorption function will

vary due to a number of factors (concentration gradient of chemical, carrier medium, type of skin, skin moisture, skin condition, etc.). If $f(t)$ could be integrated over time from the start of exposure until time T, it would yield the absorption fraction, AF, which is the fraction of the applied dose that is absorbed after time T. The absorption fraction is a cumulative number and can increase with time to a possible maximum of 1 (or 100% absorption), but due to competing processes may reach steady state long before reaching 100% absorption. Equation 2-11 then becomes:

¹⁴ This relationship is described by Fick's Law, where $J = K_p \cdot C$ where C represents the steady-state concentration of the chemical, J is the steady-state flux, and K_p is the permeability coefficient.

¹⁵ The permeability coefficient, K_p , can be experimentally calculated for a chemical and a particular barrier (e.g., skin type) by observing the

flux rate *in vitro* (typical units: mg chemical/sec-cm²), and dividing it by the concentration of the chemical in the medium in contact with the barrier (typical units: mg chemical/cm³). This allows the relationship between bulk concentration and the crossing of the chemical itself to be made. K_p has the advantage of being fairly

constant over a range of concentrations and can be used for concentrations other than the one used in the experiment. The chemical uptake rate, relating the crossing of the barrier of the chemical itself in terms of the bulk concentration, then becomes C times K_p times the surface area exposed (SA).

$$D_{int} = D_{app} \cdot AF \quad (2-12)$$

where AF is the absorption fraction in units of mass absorbed/mass applied (dimensionless).

If one assumes that all the chemical contained in the bulk material will eventually come in contact with the skin, then D_{app} equals D_{pot} and using Equation 2-12, the D_{int} equation becomes:

$$D_{int} = D_{pot} \cdot AF \quad (2-13)$$

and (using Equations 2-9 and 2-10) consequently:

$$ADD_{int} = [\bar{C} \cdot M_{medium} \cdot AF] / [BW \cdot AT] \quad (2-14)$$

where M_{medium} is the mass of the bulk material applied to the skin. For reasons explained below, this approximation will by no means always give credible results. The key is whether all the chemical contained in the bulk medium can actually contact the skin. Although with certain liquids or small amounts of material, the applied dose may be approximately equal to the potential dose, in cases where there is contact with more than a minimal amount of soil, there is research that indicates that using this approximation may cause serious error (Yang *et al.*, 1989). When this approximation does not hold, the assessor must make assumptions about how much of the bulk material actually contacts the skin, or use the first method of estimating internal dose outlined above.

Unfortunately, almost no data are available concerning the relationship between potential dose and applied dose for dermal exposures. Experimental data on absorption fractions derived for soil commonly use potential dose rather than applied dose, which may make the experimental data at least in part dependent on experimental conditions such as how much soil was applied. If the exposure assessment conditions are similar to those in the experiment, this would not usually introduce much error, but if the conditions vary widely, the error introduced may be difficult to determine.

As a practical matter, estimates of absorption fraction are often crude approximations and may be difficult to refine even if some data from experiments are available in the published literature. Typically, absorption experiments report results as an absorption fraction after a given time (e.g., 50% after 24 hours). Since absorption fraction is a function of several variables such as skin temperature, pH, moisture content, and

exposed surface area, as well as characteristics of the matrix in which the chemical occurs (e.g., soil particle size distribution, organic matter content, and moisture content), it is often difficult to make comparisons between experimental data and conditions being considered for an assessment.

With single data points, it may not be clear whether the experiment reached steady state. If several data points are available from different times in the experiment, a plot of absorption fraction vs. time may be instructive. For chemicals where data are available for steady-state conditions, the steady-state value will probably be a good approximation to use in assessments where exposure duration is at least this long, provided the conditions in the experiment are similar to those of the case being assessed. Assessors should be very cautious in applying absorption fractions for moderately absorbed chemicals (where observed experimental absorption fractions are not in the steady-state part of the cumulative curve), or in using experimental data for estimates of absorption over a much shorter duration than in the experiment.

In almost all cases, the absorption fraction method of estimating internal dose from applied dose gives only an approximation of the internal dose. The interested reader is referred to U.S. EPA (1992b) for more thorough guidance on dermal exposure assessment.

2.1.4.3. Calculating Internal Dose for Intake Processes (Especially via Respiratory and Oral Routes)

Chemicals in air, food, or drinking water normally enter the body through intake processes, then are subsequently absorbed through internal uptake processes in the lung or gastrointestinal tract. Sometimes it is necessary to estimate resulting internal dose, D_{int} , after intake. In addition, if enough is

known about the pharmacokinetics of the chemical to make addition of doses across routes a meaningful exercise, the doses must be added as internal dose, not applied dose, potential dose, or exposure.

Theoretically, one could calculate D_{int} in these cases by using an equation similar to Equation 2-7; but C in that equation would become the concentration of the chemical in the lung or gastrointestinal tract, SA would be the internal surface area involved, and K_p would be the permeability coefficient of the lung or gastrointestinal tract lining. Although data from the pharmaceutical field may be helpful in determining, for example, internal surface areas, all of the data mentioned above are not known, nor are they measurable with current instrumentation.

Because Equations 2-2 through 2-4 estimate the potential dose D_{pot} , which is the amount ingested or inhaled, and Equations 2-11 and 2-12 provide relationships between the applied dose (D_{app}) and internal dose (D_{int}), all that is necessary is a relationship between potential dose and applied dose for intake processes. Again, data on this topic are virtually nonexistent, so a common assumption is that for intake processes, the potential dose equals the applied dose. Although arguments can be made that this assumption is likely to be more nearly accurate than for the case of soil contact, the validity of this assumption is unknown at this point. Essentially, the assumption of equality means that whatever is eaten, drunk, or inhaled touches an absorption barrier inside the person.

Assuming potential dose and applied dose are approximately equal, the internal dose after intake can be estimated by combining Equations 2-2 or 2-3 and 2-10 or 2-11. Using Equations 2-3 and 2-11, this becomes:

$$D_{int} = D_{app} \cdot AF = D_{pot} \cdot AF = \bar{C} \cdot \bar{IR} \cdot ED \cdot AF \quad (2-15)$$

The ADD_{int} for the two-step intake/uptake process becomes:

$$ADD_{int} = ADD_{pot} \cdot AF = [\bar{C} \cdot \bar{IR} \cdot ED \cdot AF] / [BW \cdot AT] \quad (2-16)$$

Using average values for \bar{C} and \bar{IR} in Equations 2-15 and 2-16 involves the same assumptions and cautions as were discussed in deriving the ADD and LADD equations in the previous two sections, and of course, the same

cautions apply to the use of the absorption fraction as were outlined in section 2.1.4.2.

2.1.5. Summary of Exposure and Dose Terms With Example Units

Table 2-1 provides a summary of the exposure and dose terms discussed in section 2.1, along with examples of units commonly used.

TABLE 2-1.—EXPLANATION OF EXPOSURE AND DOSE TERMS.

Term	Refers to	Generic units	Specific example units
Exposure.....	Contact of chemical with outer boundary of a person, e.g., skin, nose, mouth.	Concentration \times time.....	Dermal: (mg chem/L water) \times (hrs of contact) (mg chem/kg soil) \times (hrs of contact) Respiratory: (ppm chem in air) \times (hrs of contact) (μ g/m ³ air) \times (days of contact) Oral: (mg chem/L water) \times (min of contact) (mg chem/kg food) (min of contact)
Potential Dose.....	Amount of a chemical contained in material ingested, air breathed, or bulk material applied to the skin.	Mass of the chemical:.....	Dermal: (mg chem/kg soil) \times (kg soil on skin) = mg chem in soil applied to skin Dose rate is mass of the chemical/time; The dose rate is sometimes normalized to body weight: mass of chemical/unit body weight \times time Respiratory: (\times g chem/m ³ air) \times (m ³ air breathed/min) \times (min exposed) = \times g chemical in air breathed Oral: (mg chem/L water) \times (L water consumed/day) \times days exposed = mg chemical ingested in water (also dose rate: mg/day)
Applied Dose.....	Amount of chemical in contact with the primary absorption boundaries (e.g., skin, lungs, gastrointestinal tract) and available for absorption.	As above.....	Dermal: (mg chem/kg soil) \times (kg soil directly touching skin) \times (% of chem in soil actually touching skin) = mg chem actually touching skin Respiratory: (\times g chem/m ³ air) \times (m ³ air directly touching lung) (% of chemical actually touching lung) = mg chemical actually touching lung absorption barrier Oral: (mg chem/kg food) \times (kg food consumed/day) \times (% of chemical touching g.i. tract) = mg chemical actually touching g.i. tract absorption barrier (also absorbed dose rate: mg/day) chemical available to organ or cell
Internal (Absorbed) Dose.....	The amount of a chemical penetrating across an absorption barrier or exchange boundary via either physical or biological processes.	As above.....	(dose rate: mg chemical available to organ/day) Dermal: mg chemical absorbed through skin Respiratory: mg chemical absorbed via lung Oral: mg chemical absorbed via g.i. tract
Delivered Dose.....	Amount of chemical available for interaction with any particular organ or cell.	As above.....	(dose rate: mg chemical absorbed/day or mg/kg \times day) mg chemical available to organ or cell (dose rate: mg chemical available to organ/day)

2.2. Approaches to Quantification of Exposure

Although exposure assessments are done for a variety of reasons (see Section 3), the quantitative exposure

estimate can be approached from three different ways:¹⁶

¹⁶These three ways are approaches for arriving at a quantitative estimate of exposure. Sometimes the approaches to assessing exposure are described in terms of "direct measures" and "indirect measures" of exposure (e.g., NRC, 1990). Measurements that actually involve sampling on or within a person, for

example, use of personal monitors and biomarkers, are termed "direct measures" of exposure. Use of models, microenvironmental measurements, and questionnaires, where measurements do not actually involve personal measurements, are termed "indirect measures" of exposure. The direct/indirect nomenclature focuses on the type of measurements being made; the scenario evaluation/point-of-contact/reconstruction nomenclature focuses on

Continued

1. The exposure can be measured at the point of contact (the outer boundary of the body) while it is taking place, measuring both exposure concentration and time of contact and integrating them (point-of-contact measurement).

2. The exposure can be estimated by separately evaluating the exposure concentration and the time of contact, then combining this information (scenario evaluation).

3. The exposure can be estimated from dose, which in turn can be reconstructed through internal indicators (biomarkers,¹⁷ body burden, excretion levels, etc.) after the exposure has taken place (reconstruction).

These three approaches to quantification of exposure (or dose) are independent, as each is based on different data. The independence of the three methods is a useful concept in verifying or validating results. Each of the three has strengths and weaknesses; using them in combination can considerably strengthen the credibility of an exposure or risk assessment. Sections 2.2.1 through 2.2.3 briefly describe some of the strengths and weaknesses of each approach.

2.2.1. Measurement of Exposure at the Point-of-Contact

Point-of-contact exposure measurement evaluates the exposure as it occurs, by measuring the chemical concentrations at the interface between the person and the environment as a function of time, resulting in an exposure profile. The best known example of the point-of-contact measurement is the radiation dosimeter. This small badge-like device measures exposure to radiation as it occurs and provides an integrated estimate of exposure for the period of time over which the measurement has been taken. Another example is the Total Exposure Assessment Methodology (TEAM) studies (U.S. EPA, 1987a) conducted by the EPA. In the TEAM studies, a small pump with a collector and absorbent was attached to a person's clothing to measure his or her exposure to airborne solvents or other pollutants as it occurred. A third example is the carbon monoxide (CO) point-of-contact measurement studies where subjects carried a small CO measuring device for several days (U.S. EPA, 1984a). Dermal patch studies and duplicate meal studies

are also point-of-contact measurement studies. In all of these examples, the measurements are taken at the interface between the person and the environment while exposure is occurring. Use of these data for estimating exposures or doses for periods that differ from those for which the data are collected (e.g., for estimates of lifetime exposures) will require some assumptions, as discussed in Section 5.3.1.

The strength of this method is that it measures exposure directly, and providing that the measurement devices are accurate, is likely to give the most accurate exposure value for the period of time over which the measurement was taken. It is often expensive, however, and measurement devices and techniques do not currently exist for all chemicals. This method may also require assumptions to be made concerning the relationship between short-term sampling and long-term exposures, if appropriate. This method is also not source-specific, a limitation when particular sources will need to be addressed by risk managers.

2.2.2. Estimates of Exposure from Scenario Evaluation

In exposure scenario evaluation, the assessor attempts to determine the concentrations of chemicals in a medium or location and link this information with the time that individuals or populations contact the chemical. The set of assumptions about how this contact takes place is an exposure scenario. In evaluating exposure scenarios, the assessor usually characterizes the chemical concentration and the time of contact separately. This may be done for a series of events, e.g., by using Equation 2-3, or using a steady-state approximation, e.g., using Equation 2-4.

The goal of chemical concentration characterization is to develop estimates of exposure concentration. This is typically accomplished indirectly by measuring, modeling, or using existing data on concentrations in the bulk media, rather than at the point of contact. Assuming the concentration in the bulk medium is the same as the exposure concentration is a clear source of potential error in the exposure estimate and must be discussed in the uncertainty analysis. Generally, the closer the medium can be measured to the point of contact (in both space and time), the less uncertainty there is in the characterization of exposure concentration.

The goal of characterizing time of contact is to identify who is exposed and to develop estimates of the

frequency and duration of exposure. Like chemical concentration characterization, this is usually done indirectly by use of demographic data, survey statistics, behavior observation, activity diaries, activity models, or, in the absence of more substantive information, assumptions about behavior.

The chemical concentration and population characterizations are ultimately combined in an exposure scenario, and there are various ways to accomplish this. One of the major problems in evaluating dose equations such as Equations 2-4 through 2-6 is that the limiting assumptions or boundary conditions used to derive them (e.g., steady-state assumptions; see section 2.1.4.) do not always hold true. Two major approaches to this problem are (1) to evaluate the exposure or dose equation under conditions where the limiting assumptions do hold true, or (2) to deal with the uncertainty caused by the divergence from the boundary conditions. As an example of the first way, the microenvironment method, usually used for evaluating air exposures, evaluates segments of time and location where the assumption of constant concentration is approximately true, then sums over all such time segments for a total exposure for the respiratory route, effectively removing some of the boundary conditions by falling back to the more general Equation 2-3. While estimates of exposure concentration and time-of-contact are still derived indirectly by this method, the concentration and time-of-contact estimates can be measured for each microenvironment. This avoids much of the error due to using average values in cases where concentration varies widely along with time of contact.¹⁸

As examples of the second approach, there are various tools used to describe uncertainty caused by parameter variation, such as Monte Carlo analysis (see section 5). Section 6 discusses some of these techniques in more detail.

One strength of the scenario evaluation approach is that it is usually the least expensive method of the three.

¹⁸ This technique still may not deal effectively with the problem of short-term "peak concentrations" exceeding some threshold leading to an acute effect. Even the averaging process used in a microenvironment may miss significant concentration spikes and average them out to lower concentrations which are apparently less toxicologically significant. A similar problem exists when evaluating sources; a "peak release" of a toxic chemical for a short time may cause serious acute effects, even though the average concentration over a longer period of time might not indicate serious chronic effects.

how the data are used to develop the dose estimate. The three-term nomenclature is used in these guidelines to highlight the point that three independent estimates of dose can be developed.

¹⁷ Biomarkers can be used to study exposure, effects, or susceptibility. The discussion of biomarkers in these guidelines is limited to their use in indicating exposure.

Also, it is particularly suited to analysis of the risk consequences of proposed actions. It is both a strength and a weakness of scenario development that the evaluation can be performed with little or no data; it is a technique that is best used when some knowledge exists about the soundness, validity, and uncertainty of the underlying assumptions.

2.2.3. Exposure Estimation by Reconstruction of Internal Dose

Exposure can also be estimated after it has taken place. If a total dose is known, or can be reconstructed, and information about intake and uptake rates is available, an average past exposure rate can be estimated. Reconstruction of dose relies on measuring internal body indicators after exposure and intake and uptake have already occurred, and using these measurements to back-calculate dose. However, the data on body burden levels or biomarkers cannot be used directly unless a relationship can be established between these levels or biomarker indications and internal dose, and interfering reactions (e.g., metabolism of unrelated chemicals) can be accounted for or ruled out. Biological tissue or fluid measurements that reveal the presence of a chemical may indicate directly that an exposure has occurred, provided the chemical is not a metabolite of other chemicals.

Biological monitoring can be used to evaluate the amount of a chemical in the body by measuring one or more of the following items. Not all of these can be measured for every chemical:

- The concentration of the chemical itself in biological tissues or sera (blood, urine, breath, hair, adipose tissue, etc.).
- The concentration of the chemical's metabolite(s).
- The biological effect that occurs as a result of human exposure to the chemical (e.g., alkylated hemoglobin or changes in enzyme induction), or
- The amount of a chemical or its metabolites bound to target molecules.

The results of biomonitoring can be used to estimate chemical uptake during a specific interval if background levels do not mask the marker and the relationships between uptake and the marker selected are known. The time of sampling for biomarkers can be critical. Establishing a correlation between exposure and the measurement of the marker, including pharmacokinetics, can help optimize the sampling conditions.

The strengths of this method are that it demonstrates that exposure to and absorption of the chemical has actually taken place, and it theoretically can give a good indication of past exposure. The

drawbacks are that it will not work for every chemical due to interferences or the reactive nature of the chemical, it has not been methodologically established for very many chemicals, data relating internal dose to exposure are needed, and it may be expensive.

2.3. Relationships of Exposure and Dose to Risk

Exposure and dose information are often combined with exposure-response or dose-response relationships to estimate risk, the probability of an adverse effect occurring. There are a variety of risk models, with various mathematical relationships between risk and dose or (less frequently) exposure. A major function of the exposure assessment as part of a risk assessment is to provide the exposure or dose values, and their interpretations.

The exposure and dose information available will often allow estimates of individual risk or population risk, or both. Presentation of risks in a risk assessment involves more than merely a numerical value, however. Risks can be described or characterized in a number of different ways. This section discusses the relationships between exposure and dose and a series of risk descriptors.

In preparing exposure information for use in a risk assessment, the use of several descriptors, including descriptors of both individual and population risk, often provides more useful information to the risk manager than a single descriptor or risk value. Developing several descriptors may require the exposure assessor to analyze and evaluate the exposure and dose information in several different ways. The exposure assessor should be aware of the purpose, scope, and level of detail of the assessment (see Sections 3.1 through 3.3) before gathering data, since the types and amounts of data needed may differ. The questions that need to be addressed as a result of the purpose of the assessment determine the type of risk descriptors used in the assessment.

2.3.1. Individual Risk

Individual risk is risk borne by individual persons within a population. Risk assessments almost always deal with more than a single individual. Frequently, individual risks are calculated for some or all of the persons in the population being studied, and are then put into the context of where they fall in the distribution of risks for the entire population. Descriptions of individual risk can take various forms, depending on the questions being addressed. For the risk manager, there are often key questions in mapping out a strategy for dealing with individual risk.

For cancer (or when possible, noncancer) assessments, the risk manager may need answers to questions such as:

- Are individuals at risk from exposure to the substances under study? Although for substances, such as carcinogens, that are assumed to have no threshold, only a zero dose would result in no excess risk; for noncarcinogens, this question can often be addressed. In the case of the use of hazard indices, where exposures or doses are compared to a reference dose or some other acceptable level, the risk descriptor would be a statement based on the ratio between the dose incurred and the reference dose.

- To what risk levels are the persons at the highest risk subjected?

- Who are these people, what are they doing, where do they live, etc., and what might be putting them at this higher risk?

- Can people with a high degree of susceptibility be identified?

- What is the average individual risk?

In addressing these questions, risk descriptors may take any of several forms:

- An estimate of the probability that an individual in the high end of the distribution may suffer an adverse effect, along with an explanation (to the extent known) of the (exposure or susceptibility) factors which result in their being in the high end;

- An estimate of the probability that an individual at the average or median risk may suffer an adverse effect; or

- An estimate of the probability that an individual will suffer an adverse effect given a specific set of exposure circumstances.

Individuals at the high end of the risk distribution are often of interest to risk managers when considering various actions to mitigate risk. These individuals often are either more susceptible to the adverse health effect than others in the population or are highly exposed individuals, or both.

Higher susceptibility may be the result of a clear difference in the way the chemical is processed by the body, or it may be the result of being in the extreme part of the normal range in metabolism for a population. It may not always be possible to identify persons or subgroups who are more susceptible than the general population. If groups of individuals who have clearly different susceptibility characteristics can be identified, they can be treated as a separate subpopulation, and the risk assessment for this subgroup may require a different dose-response relationship from the one used for the

general population. When highly susceptible individuals can be identified, but when a different dose-response relationship is not appropriate or feasible to develop, the risks for these individuals are usually treated as part of the variability of the general population.

Highly exposed individuals have been described in the literature using many different terms. Due to unclear definitions, terms such as most exposed individual,¹⁹ worst case exposure,²⁰ and reasonable worst case exposure²¹ have sometimes been applied to a variety of *ad hoc* estimates with unclear target ranges. The term most exposed individual has often been used synonymously with worst case exposure, that is, to estimate the exposure of the individual with the highest actual or possible exposure. An accurate estimate of the exposure of the person in the distribution with the highest exposure is extremely difficult to develop; uncertainty in the estimate usually increases greatly as the more extreme ends of the distribution are approached. Even using techniques such as Monte Carlo simulations can result in high uncertainty about whether the estimate is within, or above, the actual exposure distribution.

For the purpose of these guidelines, a high end exposure estimate is a plausible estimate of the individual exposure for those persons at the upper end of an exposure distribution. The intent of this designation is to convey an estimate of exposures in the upper range of the distribution, but to avoid estimates that are beyond the true distribution. Conceptually, the high end of the distribution means above the 90th

percentile of the population distribution, but not higher than the individual in the population who has the highest exposure. High-end dose estimates are described analogously.

The concept of the high end exposure, as used in this guidance, is fundamentally different from terms such as worst case, in that the estimate is by definition intended to fall on the actual (or in the case of scenarios dealing with future exposures, probable) exposure distribution.

Key Point: The primary objective when developing an estimate of high-end exposure or dose is to arrive at an estimate that will fall within the actual distribution, rather than above it. (Estimates above the distribution are bounding estimates; see section 5.3.4.1.) Often this requires professional judgment when data are sparse, but the primary objective of this type of estimator is to be within this fairly wide conceptual target range.

The relationship between answering the questions about high-end individual risk and what the exposure assessor must do to develop the descriptors is discussed in section 3.4. Individual risk descriptors will generally require the assessor to make estimates of high-end exposure or dose, and sometimes additional estimates (e.g., estimates of central tendency such as average or median exposure or dose).

Another type of individual risk descriptor results from specific sets of circumstances that can be hypothesized as part of a scenario, for example:

- What if a homeowner lives at the edge of this site for his entire life?
- What if a pesticide applicator applies this pesticide without using protective equipment?
- What if a consumer uses this product every day for ten years? Once a month? Once a week?
- What risk level will occur if we set the standard at 100 ppb?

The assumptions made in answering these assessment-specific postulated questions should not be confused with the approximations made in developing an exposure estimate for an existing population or with the adjustments in parameter values made in performing a sensitivity analysis. The assumptions in these specific questions address a purer "if/then" relationship and, as such, are more helpful in answering specific hypothetical or anecdotal questions. The answers to these postulated questions do not give information about how likely the combination of values might be in the actual population or about how many (if any) persons might actually be subjected to the calculated risk.

Exposure scenarios employing these types of postulated questions are encountered often in risk assessments, especially in those where actual exposure data are incomplete or nonexistent. Although the estimates of individual exposure derived from these assumptions provide numerical values for calculating risk, they do so more as a matter of context than a determination of actual exposure. They are not the same types of estimates as high-end exposure or risk, where some statement must be made about the likelihood of their falling within a specified range in the actual exposure or risk distribution.

2.3.2. Population Risk

Population risk refers to an estimate of the extent of harm for the population or population segment being addressed. Risk managers may need questions addressed such as the following:

- How many cases of a particular health effect might be probabilistically estimated for a population of interest during a specified time period?
- For noncarcinogens, what portion of the population exceeds the reference dose (RfD), the reference concentration (RfC), or other health concern level?
- For carcinogens, how many persons are above a certain risk level such as 10^{-6} or a series of risk levels such as 10^{-5} , 10^{-4} , etc?
- How do various subgroups fall within the distributions of exposure, dose, and risk?
- What is the risk for a particular population segment?
- Do any particular subgroups experience a high exposure, dose, or risk?

The risk descriptors for population risk can take any of several forms:

- A probabilistic projection of the estimated extent of occurrence of a particular effect for a population or segment (sometimes called "number of cases" of effect);
- A description of what part of the population (or population segment) is above a certain risk value of interest; or
- A description of the distribution of risk among various segments or subgroups of the population.

In theory, an estimate of the extent of effects a population might incur (e.g., the number of individual cases that might occur during a specified time) can be calculated by summing the individual risks for all individuals within the population or population segment of interest. The ability to calculate this estimate depends on whether the individual risks are in terms of probabilities for each individual, rather than a hazard index or other

¹⁹ The uppermost portion of the high-end exposure range has generally been the target for terms such as "most exposed individual," although actual usage has varied.

²⁰ The term "worst case exposure" has historically meant the maximum possible exposure, or where everything that can plausibly happen to maximize exposure, happens. While in actuality, this worst case exposure may fall on the uppermost point of the population distribution, in most cases, it will be somewhat higher than the individual in the population with the highest exposure. The worst case represents a hypothetical individual and an extreme set of conditions; this will usually not be observed in an actual population. The worst case and the so-called maximum exposed individual are therefore not synonymous, the former describing a statistical possibility that may or may not occur in the population, and the latter ostensibly describing an individual that does, or is thought to, exist in the population.

²¹ The lower part of the high-end exposure range, e.g., conceptually above the 90th percentile but below about the 98th percentile, has generally been the target used by those employing the term "reasonable worst case exposure." Above about the 98th percentile has been termed the "maximum exposure" range. Note that both these terms should refer to estimates of exposure on the actual distribution, not above it.

nonprobabilistic risk. The calculation also requires a great deal more information than is normally available.

For some assessments, an alternate method is used, provided certain conditions hold. An arithmetic mean dose is usually much easier to estimate than the individual doses of each person in the population or population segment, but calculating the hypothetical number of cases by using mean doses, slope factors, and population size must be done with considerable caution. If the risk varies linearly with dose, and there is no threshold below which no effect ever occurs, an estimate of the number of cases that might occur can be derived from the definition of arithmetic mean. If $A = T/n$, where A is the arithmetic mean of n numbers, and T is the sum of the same n numbers, simple rearrangement gives $T = A \times n$. If the arithmetic mean risk for the population (A) can be estimated, and the size of the population (n) is known, then this relationship can be used to calculate a probabilistic estimate of the extent of effects (T).²² Even so, several other cautions apply when using this method.

Individual risks are usually expressed on an upper bound basis, and the resulting number of cases estimated in this manner will normally be an upper bound estimate due to the nature of the risk model used. This method will not work at all for nonlinear dose-response models, such as many noncancer effects or for nonlinear carcinogenic dose-response models.

In practice, it is difficult even to establish an accurate mean health effect risk for a population. This is due to many complications, including uncertainties in using animal data for human dose-response relationships, nonlinearities in the dose-response curve, projecting incidence data from one group to another dissimilar group, etc. Although it has been common practice to estimate the number of cases of disease, especially cancer, for populations exposed to chemicals, it should be understood that these estimates are not meant to be accurate predictions of real (or actuarial) cases of disease. The estimate's value lies in framing hypothetical risk in an understandable way rather than in any literal interpretation of the term "cases."

Another population risk descriptor is a statement regarding how many people are thought to be above a certain risk level or other point of demarcation. For carcinogens, this might be an excess risk level such as 10^{-6} (or a series of levels, i.e., 10^{-6} , 10^{-4} , etc.). For noncarcinogenic risk, it might be the portion of the population that exceeds the RfD (a dose), the RfC (an exposure concentration), an effect-based level such as a lowest observed adverse effect level (LOAEL), etc. For the exposure assessor, this type of descriptor usually requires detailed information about the distribution of exposures or doses.

Other population risk descriptors address the way the risk burden is distributed among various segments of the subject population. The segments (or subgroups) could be divided by geographic location, age, sex, ethnic background, lifestyle, economic factors, or other demographic variables, or they could represent groups of persons with a typical sensitivity or susceptibility, such as asthmatics.

For assessors, this means that data may need to be evaluated for both highly exposed population segments and highly sensitive population segments. In cases involving a highly exposed population segment, the assessor might approach this question by having this segment of the population in mind when developing the descriptors of high-end exposure or dose. Usually, however, these segments are identified (either *a priori* or from inspection of the data) and then treated as separate, unique populations in themselves, with segment-specific risk descriptors (population, individual, etc.) analogous to those used for the larger population.

2.3.3. Risk Descriptors

In summary, exposure and dose information developed as part of an exposure assessment may be used in constructing risk descriptors. These are statements to convey information about risk to users of that information, primarily risk managers. Risk descriptors can be grouped as descriptors of individual risk or population risk, and within these broad categories, there are several types of descriptors. Not all descriptors are applicable to all assessments. As a matter of policy, the Agency or individual program offices within the Agency may require one or more of these descriptors to be included in specific risk assessments. Because the type of descriptor translates fairly directly into the type of analysis the exposure assessor must perform, the

exposure assessor needs to be aware of these policies. Additional information on calculating and presenting exposure estimates and risk descriptors is found in sections 5 and 7 of these Guidelines.

3. Planning an Exposure Assessment

Exposure assessments are done for a variety of purposes, and for that reason, cannot easily be regimented into a set format or protocol. Each assessment, however, uses a similar set of planning questions, and by addressing these questions the assessor will be better able to decide what is needed to perform the assessment and how to obtain and use the information required. To facilitate this planning, the exposure assessor should consider some basic questions:

Purpose: Why is the study being conducted? What questions will the study address and how will the results be used?

Scope: Where does the study area begin and end? Will inferences be made on a national, regional, or local scale? Who or what is to be monitored? What chemicals and what media will be measured, and for which individuals, populations, or population segments will estimates of exposure and dose be developed?

Level of Detail: How accurate must the exposure or dose estimate be to achieve the purpose? How detailed must the assessment be to properly account for the biological link between exposure, dose, effect, and risk, if necessary? How is the depth of the assessment limited by resources (time and money), and what is the most effective use of those resources in terms of level of detail of the various parts of the assessment?

Approach: How will exposure or dose be measured or estimated, and are these methods appropriate given the biological links among exposure, dose, effect, and risk? How will populations be characterized? How will exposure concentrations be estimated? What is known about the environmental and biological fate of the substance? What are the important exposure pathways? What is known about expected concentrations, analytical methods, and detection limits? Are the presently available analytical methods capable of detecting the chemical of interest and can they achieve the level of quality needed in the assessment? How many samples are needed? When will the samples be collected? How frequently? How will the data be handled, analyzed, and interpreted?

By addressing each of these questions, the exposure assessor will develop a clear and concise definition of study

²² Since the geometric mean (G) is defined differently, use of the geometric mean individual risk (where G does not equal A , such as is often found in environmental situations) in the above relationship will obviously give an erroneous (usually low) estimate of the total. Geometric means have appropriate uses in exposure and risk assessment, but estimating population risk in this way is not one of them.

objectives that will form the basis for further planning.

3.1. Purpose of the Exposure Assessment

The particular purpose for which an exposure assessment will be used will often have significant implications for the scope, level of detail, and approach of the assessment. Because of the complex nature of exposure assessments, a multidisciplinary approach that encompasses the expertise of a variety of scientists is necessary. Exposure assessors should seek assistance from other scientists when they lack the expertise necessary in certain areas of the assessment.

3.1.1. Using Exposure Assessments in Risk Assessment

The National Research Council (NRC, 1983) described exposure assessment as one of the four major areas of risk assessment (the others are hazard identification, dose-response assessment, and risk characterization). The primary purpose of an exposure assessment in this application is often to estimate dose, which is combined with chemical-specific dose-response data (usually from animal studies) in order to estimate risk. Depending on the purpose of the risk assessment, the exposure assessment will need to emphasize certain areas in addition to quantification of exposure and dose.

If the exposure assessment is part of a risk assessment to support regulations for specific chemical sources, such as point emission sources, consumer products, or pesticides, then the link between the source and the exposed or potentially exposed population is important. In this case, it is often necessary to trace chemicals from the source to the point of exposure by using source and fate models and exposure scenarios. By examining the individual components of a scenario, assessors can focus their efforts on the factors that contribute the most to exposure, and perhaps use the exposure assessment to select possible actions to reduce risk. For example, exposure assessments are often used to compare and select control or cleanup options. Most often the scenario evaluation is employed to estimate the residual risk associated with each of the alternatives under consideration. These estimates are compared to the baseline risk to determine the relative risk reduction of each alternative. These types of assessments can also be employed to make screening decisions about whether to further investigate a particular chemical. These assessments can also benefit from verification through the use

of personal or biological monitoring techniques.

If the exposure assessment is part of a risk assessment performed to set standards for environmental media, usually the concentration levels in the medium that pose a particular risk level are important. Normally, these assessments place less emphasis on the ultimate source of the chemical and more emphasis on linking concentration levels in the medium with exposure and dose levels of those exposed. A combination of media measurements and personal exposure monitoring could be very helpful in assessments for this purpose, since what is being sought is the relationship between the two. Modeling may also support or supplement these assessments.

If the exposure assessment is part of a risk assessment used to determine the need to remediate a waste site or chemical spill, the emphasis is on calculating the risk to an individual or small group, comparing that risk to an acceptable risk level, and if necessary determining appropriate cleanup actions to reach an acceptable risk. The source of chemical contamination may or may not be known. Although personal exposure monitoring can give a good indication of the exposure or dose at the present time, often the risk manager must make a decision that will protect health in the future. For this reason, modeling and scenario development are the primary techniques used in this type of assessment. Emphasis is usually placed on linking sources with the exposed individuals. Biological monitoring may also be helpful (in cases where the methodology is established) in determining if exposure actually results in a dose, since some chemicals are not bioavailable even if intake occurs.

If the exposure assessment is part of a risk assessment used as a screening device for setting priorities, the emphasis is more on the comparative risk levels, perhaps with the risk estimates falling into broad categories (e.g., semi-quantitative categories such as high, medium, and low). For such quick-sorting exercises, rarely are any techniques used other than modeling and scenario development. Decisions made in such cases rarely involve direct cleanup or regulatory action without further refinement of the risk assessment, so the scenario development approach can be a cost-effective way to set general priorities for future investigation of worst risk first.

If the exposure assessment is part of a risk assessment that is wholly predictive in nature, such as for the

premanufacture notice (PMN) program, a modeling and scenario development approach is recommended. In such cases, measurement of chemicals yet to be manufactured or in the environment is not possible. In this case again, the link between source and exposed individuals is emphasized.

Not only are risk assessments done for a variety of purposes, but the toxic endpoints being assessed (e.g., cancer, reproductive effects, neurotoxic effects) can also vary widely. Endpoints and other aspects of the hazard identification and dose-response relationships can have a major effect on how the exposure information must be collected and analyzed for a risk assessment. This is discussed in more detail in section 3.5.1.

3.1.2. Using Exposure Assessments for Status and Trends

Exposure assessments can also be used to determine whether exposure occurs and to monitor status and trends. The emphasis in these exposure assessments is on what the actual exposure (or dose) is at one particular time, and how the exposure changes over time. Examples of this type of assessment are occupational studies. Characteristics and special considerations for occupational studies have been discussed by the National Institute for Occupational Safety and Health (NIOSH, 1988).

Exposure status is the snapshot of exposure at a given time, usually the exposure profile of a population or population segment (perhaps a segment or statistical sample that can be studied periodically). Exposure trends show how this profile changes with time. Normally, status and trends studies make use of statistical sampling strategies to assure that changes can be interpreted meaningfully. These data are particularly useful if actions for risk amelioration and demonstration of the effectiveness of these actions can be made through exposure trend measurements.

Measurement is critical to such assessments. Personal monitoring can give the most accurate picture of exposure, but biological or media monitoring can indicate exposure levels, provided a strong link is established between the biological or media levels and the exposure levels. Usually this link is established first by correlating biological or media levels with personal monitoring data for the same population over the same period.

3.1.3. Using Exposure Assessments in Epidemiologic Studies

Exposure assessments can also be important components of epidemiologic studies, where the emphasis is on using the exposure assessment to establish exposure-incidence (or dose-effect) relationships. For this purpose, personal monitoring, biological monitoring, and scenario development have all been used. If the population under study is being currently exposed, personal monitoring or biological monitoring may be particularly helpful in establishing exposure or dose levels. If the exposure took place in the past, biological monitoring may provide useful data, provided the chemical is amenable to detection without interference or degradation, and the pharmacokinetics are known. More often, however, scenario development techniques are used to estimate exposure in the past, and often the accuracy of the estimate is limited to classifying exposure as high, medium, or low. This type of categorization is rather common, but sometimes it is very difficult to determine who belongs in a category, and to interpret the results of the study. Although epidemiologic protocols are beyond the scope of these Guidelines, the use of exposure assessment for epidemiology has been described by the World Health Organization (WHO, 1983).

3.2. Scope of the Assessment

The scope of an assessment refers to its comprehensiveness. For example, an important limitation in many exposure assessments relates to the specific chemical(s) to be evaluated. Although this seems obvious, where exposure to multiple chemicals or mixtures is possible, it is not always clear whether assessing "all" chemicals will result in a different risk value than if only certain significant chemicals are assessed and the others assumed to contribute only a minor amount to the risk. This may also be true for cases where degradation products have equal or greater toxicological concerns. In these cases, a preliminary investigation may be necessary to determine which chemicals are likely to be in high enough concentrations to cause concern, with the possible contribution of the others discussed in the uncertainty assessment. The assessor must also determine geographical boundaries, population exposed, environmental media to be considered, and exposure pathways and routes of concern.

The purpose of the exposure assessment will usually help define the scope. There are characteristics that are

unique to national exposure assessments as opposed to industry-wide or local exposure assessments. For example, exposure assessments in support of national regulations must be national in scope; exposure assessments to support cleanup decisions at a site will be local in scope. Exposure assessments to support standards for a particular medium will often concentrate on that medium's concentration levels and typical exposure pathways and routes, although the other pathways and routes are also often estimated for perspective.

3.3. Level of Detail of the Assessment

The level of detail, or depth of the assessment, is measured by the amount and resolution of the data used, and the sophistication of the analysis employed. It is determined by the purpose of the exposure assessment and the resources available to perform the assessment. Although in theory the level of detail needed can be established by determining the accuracy of the estimate required, this is rarely the case in practice. To conserve resources, most assessments are done in an iterative fashion, with a screening done first; successive iterations add more detail and sophistication. After each iteration, the question is asked, is this level of detail or degree of confidence good enough to achieve the purpose of the assessment? If the answer is no, successive iterations continue until the answer is affirmative, new input data are generated, or as is the case for many assessments, the available data, time, or resources are depleted. Resource-limited assessments should be evaluated in terms of what part of the original objectives have been accomplished, and how this affects the use of the results.

The level of detail of an exposure assessment can also be influenced by the level of sophistication or uncertainty in the assessment of health effects to be used for a risk assessment. If only very weak health information is available, a detailed, costly, and in-depth exposure assessment will in most cases be wasteful, since the most detailed information will not add significantly to the certainty of the risk assessment.

3.4. Determining the Approach for the Exposure Assessment

The intended use of the exposure assessment will generally favor one approach to quantifying exposure over the others, or suggest that two or more approaches be combined. These approaches to exposure assessment can be viewed as different ways of estimating the same exposure or dose. Each has its own unique characteristics,

strengths, and weaknesses, but the estimate should theoretically be the same, independent of the approach taken.

The point-of-contact approach requires measurements of chemical concentrations at the point where they contact the exposed individuals, and a record of the length of time of contact at each concentration. Some integrative techniques are inexpensive and easy to use (radiation badges), while others are costly and may present logistical challenges (personal continuous-sampling devices), and require public cooperation.

The scenario evaluation approach requires chemical concentration and time-of-contact data, as well as information on the exposed persons. Chemical concentration may be determined by sampling and analysis or by use of fate and transport models (including simple dilution models). Models can be particularly helpful when some analytical data are available, but resources for additional sampling are limited. Information on human behavior and physical characteristics may be assumed or obtained by interviews or other techniques from individuals who represent the population of interest.

For the reconstruction of dose approach, the exposure assessor usually uses measured body burden or specific biomarker data, and selects or constructs a biological model that uses these data to account for the chemical's behavior in the body. If a pharmacokinetic model is used, additional data on metabolic processes will be required (as well as model validation information). Information on exposure routes and relative source strengths is also helpful.

One of the goals in selecting the approach should include developing an estimate having an acceptable amount of uncertainty. In general, estimates based on quality-assured measurement data, gathered to directly answer the questions of the assessment, are likely to have less uncertainty than estimates based on indirect information. The approach selected for the assessment will determine which data are needed. All three approaches also require data on intake and uptake rates if the final product of the assessment is a calculated dose.

Sometimes more than one approach is used to estimate exposure. For example, the TEAM study combines point-of-contact measurement with the microenvironment (scenario evaluation) approach and breath measurements for the reconstruction of dose approach (U.S. EPA, 1987a). If more than one

approach is used, the assessor should consider how using each approach separately can verify or validate the others. In particular, point-of-contact measurements can be used as a check on assessments made by scenario evaluation.

3.5. Establishing the Exposure Assessment Plan

Before starting work on an exposure assessment, the assessor should have determined the purpose, scope, level of detail, and approach for the assessment, and should be able to translate these into a set of objectives. These objectives will be the foundation for the exposure assessment plan. The exposure assessment plan need not be a lengthy or formal document, especially for assessments that have a narrow scope and little detail. For more complex exposure assessments, however, it is helpful to have a written plan.

For exposure assessments being done as part of a risk assessment, the exposure assessment plan should reflect (in addition to the objectives) an understanding of how the results of the exposure assessment will be used in the risk assessment. For some assessments, three additional components may be needed: the sampling strategy (section 3.5.2), the modeling strategy (section 3.5.3), and the communications strategy (section 7.1.3).

3.5.1. Planning an Exposure Assessment as Part of a Risk Assessment

For risk assessments, exposure information must be clearly linked to the hazard identification and dose-response relationship (or exposure-response relationship; see section 3.5.4). The toxic endpoints (e.g., cancer, reproductive effects, neurotoxic effects) can vary widely, and along with other aspects of the hazard identification and dose-response relationships, can have a major effect on how the exposure information must be collected and analyzed for a risk assessment. Some of these aspects include implications of limited versus repeated exposures, dose-rate considerations, reversibility of toxicological processes, and composition of the exposed population.

• *Limited versus Repeated Exposures.* Current carcinogen risk models often use lifetime time-weighted average doses in the dose-response relationships owing to their derivation from lifetime animal studies. This does not mean cancer cannot occur after single exposures (witness the A-bomb experience), merely that exposure information must be consonant with the source of the model. Some toxic effects, however, occur after a single or a

limited number of exposures, including acute reactions such as anesthetic effects and respiratory depression or certain developmental effects following exposure during pregnancy. For developmental effects, for example, lifetime time-weighted averages have little relevance, so different types of data must be collected, in this case usually shorter-term exposure profile data during a particular time window. Consequently, the exposure assessors and scientists who conduct monitoring studies need to collaborate with those scientists who evaluate a chemical's hazard potential to assure the development of a meaningful risk assessment. If short-term peak exposures are related to the effect, then instruments used should be able to measure short-term peak concentrations. If cumulative exposure is related to the effect, long-term average sampling strategies will probably be more appropriate.

• *Dose-Rate Effects.* The use of average daily dose values (e.g., ADD, LADD) in a dose-response relationship assumes that within some limits, increments of C times T (exposure concentration times time) that are equal in magnitude are equivalent in their potential to cause an effect, regardless of the pattern of exposure (the so-called Haber's Rule; see Atherley, 1985). In those cases where toxicity depends on the dose rate, one may need a more precise determination of the time people are exposed to various concentrations and the sequence in which these exposures occur.

• *Reversibility of Toxicological Processes.* The averaging process for daily exposure assumes that repeated dosing continues to add to the risk potential. In some cases, after cessation of exposure, toxicological processes are reversible over time. In these cases, exposure assessments must provide enough information so that the risk assessor can account for the potential influence of episodic exposures.

• *Composition of the Exposed Population.* For some substances, the type of health effect may vary as a function of age or sex. Likewise, certain behaviors (e.g., smoking), diseases (e.g., asthma), and genetic traits (e.g., glucose-6-phosphate dehydrogenase deficiency) may affect the response of a person to a chemical substance. Special population segments, such as children, may also call for a specialized approach to data collection (WHO, 1986).

3.5.2. Establishing the Sampling Strategy

If the objectives of the assessment are to be met using measurements, it is important to establish the sampling

strategy before samples are actually taken. The sampling strategy includes setting data quality objectives, developing the sampling plan and design, using spiked and blank samples, assessing background levels, developing quality assurance project plans, validating previously generated data, and selecting and validating analytical methods.

3.5.2.1. Data Quality Objectives

All measurements are subject to uncertainty because of the inherent variability in the quantities being measured (e.g., spatial and temporal variability) and analytical measurement variability introduced during the measurement process through sampling and analysis. Some sources of variability can be expressed quantitatively, but others can only be described qualitatively. The larger the variability associated with individual measurements, the lower the data quality, and the greater the probability of errors in interpretation. Data quality objectives (DQOs) describe the degree of uncertainty that an exposure assessor and other scientists and management are willing to accept.

Realistic DQOs are essential. Data of insufficient quality will have little value for problem solving, while data of quality vastly in excess of what is needed to answer the questions asked provide few, if any, additional advantages. DQOs should consider data needs, cost-effectiveness, and the capability of the measurement process. The amount of data required depends on the level of detail necessary for the purpose of the assessment. Estimates of the number of samples to be taken and measurements to be made should account for expected sample variability. Finally, DQOs help clarify study objectives by compelling the exposure assessor to establish how the data will be used before they are collected.

The exposure assessor establishes data criteria by proposing limits (based on best judgment or perhaps a pilot study) on the acceptable level of uncertainty for each conclusion to be drawn from new data, considering the resources available for the study. DQOs should include:

• A clear statement of study objectives, to include an estimation of the key study parameters, identifying the hypotheses being tested, the specific aims of the study, and how the results will be used.

• The scope of study objectives, to include the minimum size of subsamples from which separate results may be calculated, and the largest unit (area,

time period, or group of people) the data will represent.

- A description of the data to be obtained, the media to be sampled, and the capabilities of the analytical methodologies.

- The acceptable probabilities and uncertainties associated with false positive and false negative statements.

- A discussion of statistics used to summarize the data; any standards, reference values, or action levels used for comparison; and a description and rationale for any mathematical or statistical procedures used.

- An estimate of the resources needed.

3.5.2.2. Sampling Plan

The sampling plan specifies how a sample is to be selected and handled. An inadequate plan will often lead to biased, unreliable, or meaningless results. Good planning, on the other hand, makes optimal use of limited resources and is more likely to produce valid results.

The sampling design specifies the number and types of samples needed to achieve DQOs. Factors to be considered in developing the sampling design include study objectives, sources of variability (e.g., temporal and spatial heterogeneity, analytical differences) and their relative magnitudes, relative costs, and practical limitations of time, cost, and personnel.

Sampling design considers the need for temporal and spatial replication, compositing (combining several samples prior to analysis), and multiple determinations on a single sample. A statistical or environmental process model may be used to allocate sampling effort in the most efficient manner.

Data may be collected using a survey or an experimental approach. It may be desirable to stratify the sample if it is suspected that differences exist between segments of the statistical population being sampled. In such cases, the stratified sampling plan assures representative samples of the obviously different parts of the sample population while reducing variance in the sample data. The survey approach estimates population exposure based on the measured exposure of a statistically representative sample of the population. In some situations the study objectives are better served by an experimental approach; this approach involves experiments designed to determine the relationship between two or more factors, (e.g., between house construction and a particular indoor air pollutant). In the experimental approach, experimental units are selected to cover a range of situations

(e.g., different housing types), but do not reflect the frequency of those units in the population of interest. An understanding of the relationship between factors gained from an experiment can be combined with other data (e.g., distribution of housing types) to estimate exposure. An advantage of the experimental approach is that it may provide more insight into underlying mechanisms which may be important in targeting regulatory action. However, as in all experimental work, one must argue that the relationships revealed apply beyond that particular experiment.

A study may use a combination of survey and experimental techniques and involve a variety of sampling procedures. A summary of methods for measuring worker exposure is found in Lynch (1985). Smith *et al.* (1987) provide guidance for field sampling of pesticides. Relevant EPA reference documents include Survey Management Handbook, Volumes I and II (U.S. EPA, 1984b); Soil Sampling Quality Assurance User's Guide (U.S. EPA, 1990a); and A Rationale for the Assessment of Errors in the Sampling of Soils (U.S. EPA, 1989a). A detailed description of methods for enumerating and characterizing populations exposed to chemical substances is contained in Methods for Assessing Exposure to Chemical Substances, Volume 4 (U.S. EPA, 1985a).

Factors to be considered in selecting sampling locations include population density, historical sampling results, patterns of environmental contamination and environmental characteristics such as stream flow or prevailing wind direction, access to the sample site, types of samples, and health and safety requirements.

The frequency and duration of sample collection will depend on whether the risk assessor is concerned with acute or chronic exposures, how rapidly contamination patterns are changing, ways in which chemicals are released into the environment, and whether and to what degree physical conditions are expected to vary in the future.

There are many sources of information on methods for selecting sampling locations. Schweitzer and Black (1985) and Schweitzer and Santolucito (1984) give statistical methods for selecting sampling locations for ground water, soil, and hazardous wastes. A practical guide for ground-water sampling (U.S. EPA, 1985b) and a handbook for stream sampling (U.S. EPA, 1986d) are also available.

The type of sample to be taken and the physical and chemical properties of the chemical of concern usually dictate

the sampling frequency. For example, determining the concentration of a volatile chemical in surface water requires a higher sampling frequency than necessary for ground water because the chemical concentration of the surface water changes more rapidly. Sampling frequency might also depend on whether the health effects of concern result from acute or chronic exposures. More frequent sampling may be needed to determine peak exposures versus average exposure.

A preliminary survey is often used to estimate the optimum number, spacing, and sampling frequency. Factors to be considered include technical objectives, resources, program schedule, types of analyses, and the constituents to be evaluated. Shaw *et al.* (1984), Sanders and Adrian (1978), and Nelson and Ward (1981) discuss statistical techniques for determining the optimal number of samples.

Sampling duration depends on the analytical method chosen, the limits of detection, the physical and chemical properties of the analyte, chemical concentration, and knowledge of transport and transformation mechanisms. Sampling duration may be extended to ensure adequate collection of a chemical at low concentration or curtailed to prevent the breakthrough of one at high concentration. Sampling duration is directly related to selection of statistical procedures, such as trend or cross-sectional analyses.

Storage stability studies with periodic sample analysis should normally be run concurrently with the storage of treated samples. However, in certain situations where chemicals are prone to break down or have high volatility, it is advisable to run a storage stability study in advance so that proper storage and maximum time of storage can be determined prior to sample collection and storage. Unless storage stability has been previously documented, samples should be analyzed as soon as possible after collection to avoid storage stability problems. Individual programs may have specific time limits on storage, depending on the types of samples being analyzed.

3.5.2.3. Quality Assurance Samples

Sampling should be planned to ensure that the samples are not biased by the introduction of field or laboratory contaminants. If sample validity is in question, all associated analytical data will be suspect. Field- and laboratory-spiked samples and blank samples should be analyzed concurrently to validate results. The plan should provide instructions clear enough so that

each worker can collect, prepare, preserve, and analyze samples according to established protocols.

Any data not significantly greater than blank sample levels should be used with considerable caution. All values should be reported as measured by the laboratory, but with appropriate caveats on blank sample levels. The method for interpreting and using the results from blank samples depends on the analyte and should be specified in the sampling plan. The following guidance is recommended:

- For volatiles and semivolatiles, no positive sample results should be reported unless the concentration of the compound in the sample exceeds 10 times the amount in any blank for the common laboratory contaminants methylene chloride, acetone, toluene, 2-butanone, and common phthalate esters. The amount for other volatiles and semivolatiles should exceed 5 times the amount in the blank (U.S. EPA, 1988d).

- For pesticides and polychlorinated biphenyls (PCBs) no positive sample results should be reported unless the concentration in the sample exceeds 5 times that in the blank (U.S. EPA, 1988d). If a pesticide or PCB is found in a blank but not in a sample, no action is taken.

- For inorganics, no positive sample results should be reported if the results are less than 5 times the amount in any blank (U.S. EPA, 1988e).

3.5.2.4. Background Level

Background presence may be due to natural or anthropogenic sources. At some sites, it is significant and must be accounted for. The exposure assessor should try to determine local background concentrations by gathering data from nearby locations clearly unaffected by the site under investigation.

When differences between a background (control area) and a target site are to be determined experimentally, the control area must be sampled with the same detail and care as the target.

3.5.2.5. Quality Assurance and Quality Control

Quality assurance (QA) assures that a product meets defined standards of quality with a stated level of confidence. QA includes quality control.

Quality assurance begins with the establishment of DQOs and continues throughout the measurement process. Each laboratory should have a QA program and, for each study, a detailed quality assurance project plan, with language clear enough to preclude confusion and misunderstanding. The

plan should list the DQOs and fully describe the analytes, all materials, methods, and procedures used, and the responsibilities of project participants. The EPA has prepared a guidance document (U.S. EPA, 1980) that describes all these elements and provides complete guidance for plan preparation.

Quality control (QC) ensures a product or service is satisfactory, dependable, and economical. A QC program should include development and strict adherence to principles of good laboratory practice, consistent use of standard operational procedures, and carefully-designed protocols for each measurement effort. The program should ensure that errors have been statistically characterized and reduced to acceptable levels.

3.5.2.6. Quality Assurance and Quality Control for Previously Generated Data

Previously generated data may be used by the exposure assessor to fulfill current needs. Any data developed through previous studies should be validated with respect to both quality and extrapolation to current use. One should consider how long ago the data were collected and whether they are still representative. The criteria for method selection and validation should also be followed when analyzing existing data. Other points considered in data evaluation include the collection protocol, analytical methods, detection limits, laboratory performance, and sample handling.

3.5.2.7. Selection and Validation of Analytical Methods

There are several major steps in the method selection and validation process. First, the assessor establishes methods requirements. Next, existing methods are reviewed for suitability to the current application. If a new method must be developed, it is subjected to field and laboratory testing to determine its performance; these tests are then repeated by other laboratories using a round robin test. Finally, the method is revised as indicated by laboratory testing. The reader is referred to Guidance for Data Useability in Risk Assessment (U.S. EPA, 1990b) for extensive discussion of this topic.

3.5.3. Establishing the Modeling Strategy

Often the most critical element of the assessment is the estimation of pollutant concentrations at exposure points. This is usually carried out by a combination of field data and mathematical modeling results. In the absence of field data, this process often relies on the results of

mathematical models (U.S. EPA, 1986e, 1987b, 1987c, 1988f, 1991b). EPA's Science Advisory Board (U.S. EPA, 1989b) has concluded that, ideally, modeling should be linked with monitoring data in regulatory assessments, although this is not always possible (e.g., for new chemicals).

A modeling strategy has several aspects, including setting objectives, model selection, obtaining and installing the code, calibrating and running the computer model, and validation and verification. Many of these aspects are analogous to the QA/QC measures applied to measurements.

3.5.3.1. Setting the Modeling Study Objectives

The first step in using a model to estimate concentrations and exposure is to clearly define the goal of the exposure assessment and how the model can help address the questions or hypotheses of the assessment. This includes a clear statement of what information the model will help estimate, and how this estimate will be used. The approach must be consistent with known project constraints (i.e., schedule, budget, and other resources).

3.5.3.2. Characterization and Model Selection

Regardless of whether models are extensively used in an assessment and a formal modeling strategy is documented in the exposure assessment plan, when computer simulation models such as fate and transport models and exposure models are used in exposure assessments, the assessor must be aware of the performance characteristics of the model and state how the exposure assessment requirements are satisfied by the model.

If models are to be used to simulate pollutant behavior at a specific site, the site must be characterized. Site characterization for any modeling study includes examining all data on the site such as source characterization, dimensions and topography of the site, location of receptor populations, meteorology, soils, geohydrology, and ranges and distributions of chemical concentrations. For exposure models that simulate both chemical concentration and time of exposure (through behavior patterns) data on these two parameters must be evaluated.

For all models, the modeler must determine if databases are available to support the site, chemical, or population characterization, and that all parameters required by the model can be obtained or reasonable default values are

available. The assessment goals and the results of the characterization step provide the technical basis for model selection.

Criteria are provided in U.S. EPA (1987b, 1988f) for selection of surface water models and ground-water models respectively; the reader is referred to these documents for details. Similar selection criteria exist for air dispersion models (U.S. EPA, 1986e, 1987c, 1991b).

A primary consideration in selecting a model is whether to perform a screening study or to perform a detailed study. A screening study makes a preliminary evaluation of a site or a general comparison between several sites. It may be generic to a type of site (i.e., an industrial segment or a climatic region) or may pertain to a specific site for which sufficient data are not available to properly characterize the site. Screening studies can help direct data collection at the site by, for example, providing an indication of the level of detection and quantification that would be required and the distances and directions from a point of release where chemical concentrations might be expected to be highest.

The value of the screening-level analysis is that it is simple to perform and may indicate that no significant contamination problem exists. Screening-level models are frequently used to get a first approximation of the concentrations that may be present. Often these models use very conservative assumptions; that is, they tend to overpredict concentrations or exposures. If the results of a conservative screening procedure indicate that predicted concentrations or exposures are less than some predetermined no-concern level, then a more detailed analysis is probably not necessary. If the screening estimates are above that level, refinement of the assumptions or a more sophisticated model are necessary for a more realistic estimate.

Screening-level models also help the user conceptualize the physical system, identify important processes, and locate available data. The assumptions used in the preliminary analysis should represent conservative conditions, such that the predicted results overestimate potential conditions, limiting false negatives. If the limited field measurements or screening analyses indicate that a contamination problem may exist, then a detailed modeling study may be useful.

A detailed study is one in which the purpose is to make a detailed evaluation of a specific site. The approach is to use the best data available to make the best estimate of spatial and temporal

distributions of chemicals. Detailed studies typically require much more data of higher quality and models of greater sophistication.

3.5.3.3. *Obtaining and Installing the Computer Code*

It may be necessary to obtain and install the computer code for a model on a specific computer system. Modern computer systems and software have a variety of differences that require changes to the source code being installed. It is essential to verify that these modifications do not change the way the model works or the results it provides. If the model is already installed and supported on a computer system to which the user has access, this step is simplified greatly.

Criteria for using a model include its demonstrated acceptability and the ease with which the model can be obtained. Factors include availability of specific models and their documentation, verification, and validation. These so-called implementation criteria relate to the practical considerations of model use and may be used to further narrow the selection of technically acceptable models.

3.5.3.4. *Calibrating and Running the Model*

Calibration is the process of adjusting selected model parameters within an expected range until the differences between model predictions and field observations are within selected criteria. Calibration is highly recommended for all operational, deterministic models. Calibration accounts for spatial variations not represented by the model formulation; functional dependencies of parameters that are either nonquantifiable, unknown, or not included in the model algorithms; or extrapolation of laboratory measurements to field conditions. Extrapolation of laboratory measurements to field conditions requires considerable care since many unknown factors may cause differences between laboratory and field.

The final step in the modeling portion of an exposure assessment is to run the model and generate the data needed to answer the questions posed in the study objectives.

Experience and familiarity with a model can also be important. This is especially true with regard to the more complex models. Detailed models can be quite complex with a large number of input variables, outputs, and computer-related requirements. It frequently takes months to years of experience to fully comprehend all aspects of a model. Consequently, it is suggested that an

exposure assessor select a familiar model if it possesses all the selection criteria, or seek the help of experienced exposure modelers.

3.5.3.5. *Model Validation*

Model validation is a process by which the accuracy of model results is compared with actual data from the system being simulated. There are numerous levels of validation of an environmental fate model, for example, such as verifying that the transport and transformation concepts are appropriately represented in the mathematical equations, verifying that the computer code is free from error, testing the model against laboratory microcosms, running field tests under controlled conditions, running general field tests, and repeatedly comparing field data to the modeling results under a variety of conditions and chemicals. In essence, validation is an independent test of how well the model (with its calibrated parameters) represents the important processes occurring in the natural system. Although field and environmental conditions are often different during the validation step, parameters fixed as a result of calibration are not readjusted during validation.²³

The performance of models (their ability to represent measured data) is often dramatically influenced by site characterization and how models represent such characteristics. Characterizing complex, heterogeneous physical systems presents major challenges; modeling representations of such systems must be evaluated in light of that difficulty. In many cases, the apparent inability to model a system is caused by incomplete physical characterization of the system. In other cases the uncertainties cannot be readily apportioned between the model per se and the model's input data.

In addition to comparing model results with actual data (thus illustrating accuracy, bias, etc.), the model validation process provides information about conditions under which a simulation will be acceptable and accurate, and under what conditions it should not be used at all. All models have specific ranges of application and specific classes of chemicals for which they are appropriate. Assessors should be aware of these limitations as they develop modeling strategies.

²³ In other words, a fundamental rule is that a model should not be validated using data that were already used to generate or calibrate the model, since doing so would not be an independent test.

3.5.4. Planning an Exposure Assessment to Assess Past Exposures

In addition to the considerations discussed in sections 3.5.1 through 3.5.3, if the data are being collected to assess past exposures, such as in epidemiologic studies, they need to be representative of the past exposure conditions, which may have changed with time. The scope and level of detail of the assessment depends greatly on the availability and quality of past data. Several approaches for determining and estimating past exposure are provided in the literature (Waxweiler *et al.*, 1988; Stern *et al.*, 1986; NIOSH, 1988; Greife *et al.*, 1988; Hornung and Meinhardt, 1987).

4. Gathering and Developing Data for Exposure Assessments

The information needed to perform an exposure assessment will depend on the approach(es) selected in the planning stage (section 3). For those assessments using point-of-contact measurements, the information includes:

- Measured exposure concentrations and duration of contact.

For assessments using the scenario evaluation method for estimating exposures, the needed information includes:

- Information on chemical concentrations in media, usually desirable in the format of a concentration-time-location profile.
- Information on persons who are exposed and the duration of contact with various concentrations.

For assessments estimating exposure from dose, the information includes:

- Biomarker data.
- Pharmacokinetic relationships, including the data to support pharmacokinetic models.

If dose is to be calculated, data are needed on:

- Intake and uptake, usually in the form of rates.

Information on both natural and anthropogenic sources is usually helpful.

If the agent has natural sources, the contribution of these to environmental concentrations may be relevant. These background concentrations may be particularly important when the results of toxicity tests show a threshold or distinctly nonlinear dose-response relationship. In a situation where only relative or additional risk is considered, background levels may not be relevant.

4.1. Measurement Data for Point-of-Contact Assessments

This approach requires that chemical concentrations be measured at the interface between the person and the environment, usually through the use of personal monitors; there are currently no models to assist in the process of obtaining the concentration-time data itself. The chemical concentrations contacted in the media are measured by sampling the individual's breathing zone, food, and water. These methodologies were originally developed for occupational monitoring; they may have to be modified for exposures outside the workplace. An example of this is the development of a small pump and collector used in the TEAM studies (U.S. EPA, 1987a). In order to conduct these studies, a monitoring device had to be developed that was sufficiently small and lightweight so that it could be worn by the subjects.

The Total Human Exposure and Indoor Air Quality (U.S. EPA, 1988h) report is a useful bibliography covering models, field data, and emerging research methodologies, as well as new techniques for accurately determining exposure at nonoccupational levels.

New data for a particular exposure assessment may be developed through the use of point-of-contact methods, or data from prior studies can sometimes be used. In determining whether existing point-of-contact monitoring data can be used in another assessment, the assessor must consider the factors that

existed in the original study and that influenced the exposure levels measured. Some of these factors are proximity to sources, activities of the studied individuals, time of day, season, and weather conditions.

Point-of-contact data are valuable in evaluating overall population exposure and checking the credibility of exposure estimates generated by other methods.

4.2. Obtaining Chemical Concentration Information

The distribution of chemical concentrations is used to estimate the concentration that comes in contact with the individual(s) at any given time and place. This can be done through personal monitoring, but for a variety of reasons, in a given assessment, personal monitoring may not be feasible. Alternative methods involve measuring the concentration in the media, or modeling the concentration distribution based on source strength, media transport, and chemical transformation processes. For exposure scenario evaluation, measurements and modeling of media concentrations are often used together.

Many types of measurements can be used to help determine the distribution of chemical concentrations in media. They can be measurements of the concentrations in the media themselves, measurements of source strength, or measurements of environmental fate processes which will allow the assessor to use a model to estimate the concentration in the media at the point of contact. Table 4-1 illustrates some of the types of measurements used by exposure assessors, along with notes concerning what additional information is usually needed to use these measurements in estimating exposure or dose. For epidemiologic studies, questionnaires are often used when data are not measurable or are otherwise unavailable.

TABLE 4-1.—EXAMPLES OF TYPES OF MEASUREMENTS TO CHARACTERIZE EXPOSURE-RELATED MEDIA AND PARAMETERS.*

Type of measurement (sample)	Usually attempts to characterize (whole)	Examples	Typical information needed to characterize exposure
A. For Use In Exposure Scenario Evaluation:			
1. Fixed-Location Monitoring.....	Environmental medium; samples used to establish long-term indications of media quality and trends.	National Stream Quality Accounting Network (NASQAN), ^a water quality networks, air quality networks.	Population location and activities relative to monitoring locations; fate of pollutants over distance between monitoring and point of exposure; time variation of pollutant concentration at point of exposure

TABLE 4-1.—EXAMPLES OF TYPES OF MEASUREMENTS TO CHARACTERIZE EXPOSURE-RELATED MEDIA AND PARAMETERS.^a—Continued

Type of measurement (sample)	Usually attempts to characterize (whole)	Examples	Typical information needed to characterize exposure
2. Short-Term Media Monitoring.....	Environmental or ambient medium; samples used to establish a snapshot of quality of medium over relatively short time.	Special studies of environmental media, indoor air.	Population location and activities (this is critical since it must be closely matched to variations in concentrations due to short period of study); fate of pollutants between measurement point and point of exposure; time variation of pollutant concentration at point of exposure.
3. Source Monitoring of Facilities.....	Release rates to the environment from sources (facilities). Often given in terms of relationships between release amounts and various operating parameters of the facilities.	Stack sampling, effluent sampling, leachate sampling from landfills, incinerator ash sampling, fugitive emissions sampling, pollution control device sampling.	Fate of pollutants from point of entry into the environment to point of exposure; population location and activities; time variation of release.
4. Food Samples (also see #11 below).	Concentrations of contaminants in food supply.	FDA Total Diet Study Program, ^c market basket studies, shelf studies, cooked-food diet sampling.	Dietary habits of various age, sex, or cultural groups. Relationship between food items sampled and groups (geographic, ethnic, demographic) studied. Relationships between concentrations in uncooked versus prepared food.
5. Drinking Water Samples.....	Concentrations of pollutants in drinking water supply.	Ground Water Supply Survey, ^d Community Water Supply Survey, ^e tap water.	Fate and distribution of pollutants from point of sample to point of consumption. Population served by specific facilities and consumption rates. For exposure due to other uses (e.g., cooking and showering), need to know activity patterns and volatilization rates.
6. Consumer Products.....	Concentration levels of various products.	Shelf surveys, e.g., solvent concentration in household cleaners ^f .	Establish use patterns and/or market share of particular products, individual exposure at various usage levels, extent of passive exposure.
7. Breathing Zone Measurements.....	Exposure to airborne chemicals.....	Industrial hygiene studies, occupational surveys, indoor air studies..	Location, activities, and time spent relative to monitoring locations. Protective measures/avoidance.
8. Microenvironmental Studies.....	Ambient medium in a defined area, e.g., kitchen, automobile interior, office setting, parking lot.	Special studies of indoor air, house dust, contaminated surfaces, radon measurements, office building studies.	Activities of study populations relative to monitoring locations and time exposed.
9. Surface Soil Sample.....	Degree of contamination of soil available for contact.	Soil samples at contaminated sites.....	Fate of pollution on/in soil; activities of potentially exposed populations.
10. Soil Core.....	Soil including pollution available for ground-water contamination; can be an indication of quality and trends over time.	Soil sampling at hazardous waste sites.....	Fate of substance in soil; speciation and bioavailability, contact and ingestion rates as a function of activity patterns and age.
11. Fish Tissue.....	Extent of contamination of edible fish tissue.	National Shellfish Survey ^g	Relationship of samples to food supply for individuals or population of interest; consumption habits; preparation habits.
B. For Use in Point-of-Contact Measurement			
1. Air Pump/Particulates and Vapors....	Exposure of an individual or population via the air medium.	TEAM study, ^h carbon monoxide study, ⁱ Breathing zone sampling in industrial settings.	Direct measurement of individual exposure during time sampled. In order to characterize exposure to population, relationships between individuals and the population must be established as well as relationships between times sampled and other times for the same individuals, and relationships between sampled individuals and other populations. In order to make these links, activities of the sampled individuals compared to populations characterized are needed in some detail.
2. Passive Vapor Sampling.....	Same as above.....	Same as above.....	Same as above.
3. Split Sample Food/Split Sample Drinking Water.	Exposures of an individual or population via ingestion..	TEAM study ^j	Same as above.
4. Skin Patch Samples.....	Dermal exposure of an individual or population.	Pesticide Applicator Survey ^k	(1) Same as above. (2) Skin penetration.

TABLE 4-1.—EXAMPLES OF TYPES OF MEASUREMENTS TO CHARACTERIZE EXPOSURE-RELATED MEDIA AND PARAMETERS.^a—Continued

Type of measurement (sample)	Usually attempts to characterize (whole)	Examples	Typical information needed to characterize exposure
C. For Use in Exposure Estimation from Reconstructed Dose:			
1. Breath.....	Total internal dose for individuals or population (usually indicative of relatively recent exposures).	Measurement of volatile organic chemicals (VOCs), alcohol. (Usually limited to volatile compounds).	(1) Relationship between individuals and population; exposure history (i.e., steady-state or not) pharmacokinetics (chemical half-life), possible storage reservoirs within the body. (2) Relationship between breath content and body burden.
2. Blood.....	Total internal dose for individuals or population (may be indicative of either relatively recent exposures to fat-soluble organics or long term body burden for metals).	Lead studies, pesticides, heavy metals (usually best for soluble compounds, although blood lipid analysis may reveal lipophilic compounds).	(1) Same as above. (2) Relationship between blood content and body burden.
3. Adipose.....	Total internal dose for individuals or population (usually indicative of long-term averages for fat-soluble organics).	NHATS, ¹ dioxin studies, PCBs (usually limited to lipophilic compounds).	(1) Same as above. (2) Relationship between adipose content and body burden.
4. Nails, Hair.....	Total internal dose for individuals or population (usually indicative of past exposure in weeks to months range; can sometimes be used to evaluate exposure patterns).	Heavy metal studies (usually limited to metals).	(1) Same as above. (2) Relationship between nails, hair content and body burden.
5. Urine.....	Total internal dose for individuals or population (usually indicative of elimination rates); time from exposure to appearance in urine may vary, depending on chemical.	Studies of tetrachloroethylene ^m and trichloroethylene ⁿ .	(1) Same as above. (2) Relationship between urine content and body burden.

^a To characterize dose, intake or uptake information is also needed (see Section 2). ^b U.S. EPA (1985c).

^c U.S. EPA (1986f). ^d U.S. EPA (1985c). ^e U.S. EPA (1985d). ^f U.S. EPA (1985a).

^g U.S. EPA (1986f). ^h U.S. EPA (1987a). ⁱ U.S. EPA (1987a). ^j U.S. EPA (1987a).

^k U.S. EPA (1987d). ^l U.S. EPA (1986g). ^m U.S. EPA (1986h). ⁿ U.S. EPA (1987e).

4.2.1. Concentration Measurements in Environmental Media

Measured concentration data can be generated for the exposure assessment by a new field study, or by evaluating concentration data from completed field study results and using them to estimate concentrations. Media measurements taken close to the point of contact with the individual(s) in space and time are preferable to measurements far removed geographically or temporally. As the distance from the point of contact increases, the certainty of the data at the point of contact usually decreases, and the obligation for the assessor to show relevance of the data to the assessment at hand becomes greater. For example, an outdoor air measurement, no matter how close it is taken to the point of contact, cannot by itself adequately characterize indoor exposure.

Concentrations can vary considerably from place to place, seasonally, and over time due to changing emission and use patterns. This needs to be considered not only when designing studies to collect new data, but especially when evaluating the applicability of existing measurements as estimates of exposure concentrations in a new assessment. It is a particular concern when the measurement data

will be used to extrapolate to long time periods such as a lifetime. Transport and dispersion models are frequently used to help answer these questions.

The exposure assessor is likely to encounter several different types of measurements. One type of measurement used for general indications and trends of concentrations is outdoor fixed-location monitoring. This measurement is used by EPA and other groups to provide a record of pollutant concentration at one place over time. Nationwide air and water monitoring programs have been established so that baseline values in these environmental media can be documented. Although it is not practical to set up a national monitoring network to gather data for a particular exposure assessment, the data from existing networks can be evaluated for relevance to an exposure assessment. These data are usually somewhat removed, and often far removed, from the point of contact. Adapting data from previous studies usually presents challenges similar to those encountered when using network data. If new data are needed for the assessment, studies measuring specific chemicals at specific locations and times can be conducted.

Contaminant concentrations in indoor air can vary as much or more than those in outdoor air. Consequently, indoor

exposure is best represented by measurements taken at the point of contact. However, because pollutants such as carbon monoxide can exhibit substantial indoor penetration, indoor exposure estimates should consider potential outdoor as well as indoor sources of the contaminant(s) under evaluation.

Food and drinking water measurements can also be made. General characterization of these media, such as market basket studies (where representative diets are characterized), shelf studies (where foodstuffs are taken from store shelves and analyzed), or drinking water quality surveys, are usually far removed from the point of contact for an individual, but may be useful in evaluating exposure concentrations over a large population. Closer to the point of contact would be measurements of tap water or foodstuffs in a home, and how they are used. In evaluating the relevance of data from previous studies, variations in the distribution systems must be considered as well as the space-time proximity.

Consumer or industrial product analysis is sometimes done to characterize the concentrations of chemicals in products. The formulation of products can change substantially over time, similar products do not

necessarily have similar formulations, and regional differences in product formulation can also occur. These should be considered when determining relevance of extant data and when setting up sampling plans to gather new data.

Another type of concentration measurement is the microenvironmental measurement. Rather than using measurements to characterize the entire medium, this approach defines specific zones in which the concentration in the medium of interest is thought to be relatively homogenous, then characterizes the concentration in that zone. Typical microenvironments include the home or parts of the home, office, automobile, or other indoor settings. Microenvironments can also be divided into time segments (e.g., kitchen-day, kitchen-night). This approach can produce measurements that are closely linked with the point of contact both in location and time, especially when new data are generated for a particular exposure assessment. The more specific the microenvironment, however, the greater the burden on the exposure assessor to establish that the measurements are representative of the population of interest. Adapting existing data bases in this area to a particular exposure assessment requires the usual evaluation discussed throughout this section.

The concentration measurement that provides the closest link to the actual point of contact uses personal monitoring, which is discussed in section 4.3.

4.2.2. Use of Models for Concentration Estimation

If concentrations in the media cannot be measured, they can frequently be estimated indirectly by using related measurements and models. To accomplish this, source and fate information are usually needed. Source characterization data are used as input to transport and transformation models (environmental fate models). These models use a combination of general relationships and situation-specific information to estimate concentrations. In exposure assessments, mathematical models are used extensively to calculate environmental fate and transport, concentrations of chemicals in different environmental media, the distribution of concentrations over space and time, indoor air levels of chemicals, concentrations in foods, etc. In determining the relevance of this type of model for estimating concentrations, the same rules apply as for the measurements of concentrations discussed in the previous section. When

concentrations in the media are available, models can be used to interpolate concentrations between measurements. Because models rely on indirect measurements and data remote from the point of contact, statistically valid analytical measurements take precedence when discrepancies arise. When it is necessary to estimate contributions of individual sources to overall concentrations, models are commonly used.

Source characterization measurements usually determine the rate of release of chemicals into the environment from a point of emission such as an incinerator, landfill, industrial facility, or other source. Often these measurements are used to estimate emission factors, or a relationship between releases and facility operations. Since emission factors are usually averages over time, the assessor must determine whether given emission factors from previous work are relevant to the time specificity and source type needed for the exposure assessment. Generally, emission factors are more useful for long-term average emission calculations, and become less useful when applied to intermittent or short-term exposures.

Environmental fate measurements can be either field measurements (field degradation studies, for example) or laboratory measurements (partition coefficients, hydrolysis, or biodegradation rates, etc.). Approximations for these can sometimes also be calculated (Lyman *et al.*, 1982).

Environmental fate models calculate estimated concentrations in media that in turn are linked to the concentrations at the point of contact. The use of estimated properties or rates adds to the uncertainty in the exposure concentration estimate. When assessors use these methods to estimate exposures, uncertainties attributable to the model and the validation status of the model must be clearly discussed in the uncertainty section (see discussion in section 6).

4.2.3. Selection of Models for Environmental Concentrations

Selection of an appropriate model is essential for successful simulation of chemical concentrations. In most cases assessors will be able to choose between several models, any of which could be used to estimate environmental concentrations. There is no right model; there may not even be a best model. There are, however, several factors that will help in selecting an appropriate model for the study. The assessor should consider the objectives of the study, the

technical capabilities of the models, how readily the models can be obtained, and how difficult each is to use (U.S. EPA, 1987b, 1988f, 1991b).

The primary consideration in selecting a model is the objective of the exposure assessment. The associated schedule, budget, and other resource constraints will also affect model selection options. Models are available to support both screening-level and detailed, site-specific studies. Screening models can provide quick, easy, and cost-effective estimates of environmental concentrations. They can support data collection efforts at the site by indicating the required level of detection and quantification and the locations where chemical concentrations are expected to be highest. They are also used to interpolate chemical concentrations between measurements. Where study objectives require the best estimates of spatial and temporal distributions of chemicals, more sophisticated models are available. These models require more and better data to characterize the site, and therefore site-specific data may be needed in order to use them.

The technical capabilities of a model are expressed in its ability to simulate site-specific contaminant transport and transformation processes. The model must be able to simulate the relevant processes occurring within the specified environmental setting. It must adequately represent the physical setting (e.g., the geometric configuration of hydrogeological systems, river widths and depths, soil profiles, meteorological patterns, etc.) and the chemical transformation processes. Field data from the area where doses are to be estimated are necessary to define the input parameters required to use the models. In cases in which these data are not available, parameter values representative of field conditions should be used as defaults. Assumptions of homogeneity and simplification of site geometry may allow use of simpler models.

In addition, it is important to thoroughly understand the performance characteristics of the model used. This is especially true with regard to the more complex models. Detailed models can be quite complex with a large number of input variables, outputs, and computer-related requirements.

4.3. Estimating Duration of Contact

As discussed in section 2, the duration of contact is linked to a particular exposure concentration to estimate exposure. Depending on the purpose of the assessment and the confidence

needed in the accuracy of the final estimate, several approaches for obtaining estimates of duration of contact can be used.

Ideally, the time that the individual is in contact with a chemical would be observed and recorded, and linked to the concentrations of the chemical during those time segments. Although it is sometimes feasible to do this (by point-of-contact measurement, see section 4.1.), many times it is not. In those cases, as in concentration characterization, the duration of contact must be estimated by using data that may be somewhat removed from the actual point of contact, and assumptions must be made as to the relevance of the data.

It is common for the estimate of duration of contact at a given concentration to be the single largest source of uncertainty in an exposure assessment.²⁴ The exposure assessor, in developing or selecting data for making estimates of duration of contact, must often assume that the available data adequately represent exposure.

4.3.1. Observation and Survey Data

Observation and recording of activities, including location-time data, are likely to be the types of data collection closest to the point of contact. This can be done by an observer or the person(s) being evaluated for exposure, and can be done for an individual, a population segment, or a population. The usual method for obtaining these data for population segments or populations is survey questionnaires. Surveys can be performed as part of the data-gathering efforts of the exposure assessment, or existing survey data can be used if appropriate.

There are several approaches used in activity surveys, including diaries, respondent or third-party estimates, momentary sampling, videomonitoring, and behavioral meters. The diary approach, probably the most powerful method for developing activity patterns, provides a sequential record of a person's activities during a specified time period. Typical time-diary studies are done across a day or a week. Diary forms are designed to have respondents report all their activities and locations for that period. Carefully designed forms are especially important for diary studies to ensure that data reported by each individual are comparable. The

resulting time budget is a sample of activity that can be used to characterize an individual's behavior, activities, or other features during the observation period. Sequential activity monitoring forms the basis of an activity profile.

Several studies have demonstrated the reliability of the diary method in terms of its ability to produce similar estimates. One study (Robinson, 1977) found a 0.85 correlation between diary estimates using the yesterday and tomorrow approaches and a 0.86 correlation between overall estimates. However, no definitive study has established the validity of time-diary data.

Questionnaires are used for direct questions to collect the basic data needed. Questionnaire design is a complex and subtle process, and should only be attempted with the help of professionals well-versed in survey techniques. A useful set of guidelines is provided in the Survey Management Handbook (U.S. EPA, 1984b).

Respondent estimates are the least expensive and most commonly used questionnaire alternative. Respondents are simply asked to estimate the time they spend at a particular activity. Basically, the question is, how many hours did you spend doing this activity (or in this location or using a certain product)? In exposure studies, respondents may be asked how often they use a chemical or product of interest or perform a specific activity. These data are less precise and likely to be somewhat less accurate than a carefully conducted diary approach.

At a less demanding level, respondents may be asked whether their homes contain items of interest (pesticides, etc.). Since this information is not time-of-activity data, it is more useful in characterizing whether the chemical of interest is present. It does, however, give the assessor some indication that use may occur.

Estimates from other respondents (third parties) use essentially the same approach, except that other informants respond for that individual. Here the question is how many hours per week does the target person spend doing this activity?

Momentary (beeper) sampling or telephone-coincidental techniques ask respondents to give only brief reports for a specific moment — usually the moment the respondent's home telephone or beeper sounds. This approach is limited to times when people are at home or able to carry beepers with them.

Methods that use behavioral meter or monitoring devices are probably the

most expensive approach, since they require the use or development of equipment, respondent agreement to use such equipment, and technical help to install or adjust the equipment.

The Exposure Factors Handbook (U.S. EPA, 1989c) contains a summary of published data on activity patterns along with citations. Note that the summary data and the mean values cited are for the data sets included in the Handbook, and may or may not be appropriate for any given assessment.

4.3.2. Developing Other Estimates of Duration of Contact

When activity surveys cannot be used to estimate duration of contact, it may be estimated from more indirect data. This is the least expensive and most commonly used approach for generating estimates of duration of contact; it is also the least accurate. But for some situations, such as assessing the risk to new chemicals being introduced into the marketplace or in assessing future possible uses of contaminated sites, it is the only approach that can be used.

In general, the methods used to make these estimates fall into two areas: (1) those where the time it takes to perform an activity is itself estimated, and (2) those where an average duration of contact is estimated by combining the time of a unit activity with data on the use of a product or commodity.

Methods that try to estimate the time of a particular activity include general time-and-motion studies that might be adapted for use in an exposure assessment, general marketing data which include time of use, anecdotal information, personal experience, and assumptions about the amount of time it takes to perform an activity.

Methods that estimate average times for activities from product or commodity use usually interpret data on product sales or marketing surveys, water use, general food sales, etc. Information on use can be combined with an estimate of the number of persons using the product to estimate the average consumption of the product. If an estimate of the duration of contact with one unit (product, gallon of water, etc.) can be made, this can then be multiplied by the average number of units consumed to arrive at an estimate of average duration of contact for each individual.

Duration-of-contact estimates based on data collected close to the actual point of contact are preferable to those based on indirect measurements; both of these are preferred to estimates based on assumptions alone. This hierarchy is

²⁴ Conversely, it may be stated that the largest source of uncertainty is the concentration for a given exposure duration. Often, however, the concentration in the media is known with more certainty than the activities of the individual(s) exposed.

useful in both the data-gathering process and uncertainty analysis.

4.4. Obtaining Data on Body Burden or Biomarkers

Body burden or biomarker data denote the presence of the chemical inside the body of exposed individuals. In a reconstructive assessment, these data, in conjunction with other environmental monitoring data, may provide a better estimate of exposure.

A biomarker of exposure has been defined as an exogenous substance or its metabolite or the product of an interaction between a xenobiotic agent and some target molecule or cell that is measured in a compartment within an organism (NRC, 1989a). Examples of simple direct biomarkers include the chemical itself in body fluid, tissue, or breath. Measurable changes in the physiology of the organism can also constitute markers of exposure. Examples include changes in a particular enzyme synthesis and activity. The interaction of xenobiotic compounds with physiological receptors can produce measurable complexes which also serve as exposure biomarkers. Other markers of exposure include xenobiotic species adducted to protein or DNA, as well as a variety of genotoxicity endpoints, such as micronuclei and mutation. Some biomarkers are specific to a given chemical while others may result from exposure to numerous individual or classes of compounds.

Biomarker data alone do not usually constitute a complete exposure assessment, since these data must be associated with external exposures. However, biomarker data complement other environmental monitoring data and modeling activities in estimating exposure.

4.5. Obtaining Data for Pharmacokinetic Relationships

To estimate dose from exposure, one must understand the pharmacokinetics of the chemical of interest. This is particularly true when comparing risks resulting from different exposure situations. Two widely different exposure profiles for the same chemical may have the same integrated exposure (area under the curve), but may not result in the same internal dose due to variations in disposition of the chemical under the two profiles. For example, enzymes that normally could metabolize low concentrations of a chemical may be saturated when the chemical is absorbed in high doses, resulting in a higher dose delivered to target tissues. The result of these two exposures may even be a different toxicological

endpoint, if pharmacokinetic sensitivities are severe enough.

An iterative approach, including both monitoring and modeling, is necessary for proper data generation and analysis. Data collection includes monitoring of environmental media, personal exposure, biomarkers, and pharmacokinetic data. It may involve monitoring for the chemical, metabolites, or the target biomarker. Monitoring activities must be designed to yield data that are useful for model formulation and validation. Modeling activities must be designed to simulate processes that can be monitored with available techniques. The pharmacokinetic data necessary for model development are usually obtained from laboratory studies with animals. The data are generated in experiments designed to estimate such model parameters as the time course of the process, absorption, distribution, metabolism, and elimination of the chemical. These data, and the pharmacokinetic models developed from them, are necessary to interpret field biomarker data.

4.6. Obtaining Data on Intake and Uptake

The Exposure Factors Handbook (U.S. EPA, 1989c) presents statistical data on many of the factors used in assessing exposure, including intake rates, and provides citations for the primary references. Some of these data were developed by researchers using approaches discussed in Section 4.2.1 (for example, Pao *et al.* (1982) used the diary approach in a study of food consumption). Intake factors included are:

- Drinking water consumption rates;
- Consumption rates for homegrown fruits, vegetables, beef, and dairy products;
- Consumption rates for recreationally caught fish and shellfish;
- Incidental soil ingestion rates;
- Pulmonary ventilation rates; and
- Surface areas of various parts of the human body.

The Exposure Factors Handbook is being updated to encompass additional factors and to include new research data on the factors currently covered. It also provides default parameter values that can be used when site-specific data are not available. Obviously, general default values should not be used in place of known, valid data that are more relevant to the assessment being done.

5. Using Data to Determine or Estimate Exposure and Dose

Collecting and assembling data, as discussed in the previous section, is

often an iterative process. Once the data are assembled, inferences can be made about exposure concentrations, times of contact, and exposures to persons other than those for whom data are available. During this process, there usually will be gaps in information that can be filled by making a series of assumptions. If these gaps are in areas critical to the accuracy of the assessment, further data collection may be necessary.

Once an acceptable data set²⁵ is available, the assessor can calculate exposure or dose. Depending on the method used to quantify exposure, there are several ways to calculate exposure and dose. This chapter will discuss making inferences (section 5.1), assumptions (section 5.2), and calculations (section 5.3).

5.1. Use of Data in Making Inferences for Exposure Assessments

Inferences are generalizations that go beyond the information contained in a data set. The credibility of an inference is often related to the method used to make it and the supporting data. Anecdotal information is the source of one type of inference, but the assessor has only limited knowledge of how well one anecdote represents the realm of possibilities, so anecdotes as a basis for inference should be used only with considerable caution. Professional judgment is usually preferred to anecdotes assuming that it is based on experience representing a variety of conditions. Statistical inferences also are generalizations that go beyond the data set. They may take any of several forms (see any statistics textbook for examples), but unlike those described above, a statistical inference will usually include a measure of how certain it is. For that reason, statistical inferences are often preferable to anecdotes or professional judgment provided the data are shown to be relevant and adequate.

As discussed above, the primary use of data from exposure-related measurements is to infer more general information about exposure concentrations, contact times, exposures, or doses. For example, measured concentrations in a medium can be used to infer what the concentration might be at the point of contact, which may not have been measured directly. Point-of-contact measurement data for one group of people may be used to infer the

²⁵ An acceptable data set is one that is consistent with the scope, depth, and purpose of the assessment, and is both relevant and adequate as discussed in Section 5.1.

exposures of a similar group, or to infer what the exposures of the same group might be at different times.

In all cases, the exposure assessor must have a clear picture of the relationship between the data at hand and what is being characterized by inference. For example, surface water concentration data alone, although essential for characterizing the medium itself, are not necessarily useful for inferring exposures from surface water, since other information is necessary to complete the link between surface water and exposure. But the medium's characteristics (over space and time) can be used, along with the location and activities of individuals or populations, to estimate exposures. Samples taken for exposure assessment may be designed to characterize different aspects (or components) of exposure. For example, a sample taken as a point-of-contact exposure measurement is qualitatively different from a sample of an environmental medium or body fluid.

Different measurements taken under the general category of exposure-related measurements cannot necessarily all be used in the same way. The exposure assessor must explain the relationship between the sample data and the inferences or conclusions being drawn from them. In order to do this, data relevance, adequacy, and uncertainty must be evaluated.

5.1.1. Relevance of Data for the Intended Exposure Assessment

When making inferences from a data set, the assessor must establish a clear link between the data and the inference. When statistically based sampling is used to generate data, relevance is a function of how well the sample represents the medium or parameter being characterized. When planning data collection for an exposure assessment, the assessor can use information about the inferences that will be made to select the best measurement techniques. In many cases data are also available from earlier studies. The assessor must determine (and state) how relevant the available data are to the current assessment; this is usually easier for new data than for previously collected information.

5.1.2. Adequacy of Data for the Intended Assessment

Table 4-1 in the previous section illustrated how different types of measurements may be used to characterize a variety of concentrations, contact times, and intake or uptake parameters. Nevertheless, just because certain types of measurements generally can be used to make certain inferences,

there is no guarantee that this can always be done. The adequacy of the data to make inferences is determined by evaluating the amount of data available and the accuracy of the data. Evaluation of the adequacy of data will ensure that the exposure assessment is conducted with data of known quality.

In general, inadequate data should not be used, but when it can be demonstrated that the inadequacies do not affect results, it is sometimes possible to use such data. In these cases, an explanation should be given as to why the inadequacies do not invalidate conclusions drawn from them. In some cases, even seriously inadequate or only partially relevant data may be the only data available, and some information may be gained from their consideration. It may not be possible to discard these data entirely unless better data are available. If these data are used, the uncertainties and resulting limitations of the inferences should be clearly stated. If data are rejected for use in favor of better data, the rationale for rejection should be clearly stated and the basis for retaining the selected data should be documented. QA/QC considerations are paramount in considerations of which data to keep and which to discard.

Outliers should not be eliminated from data analysis procedures unless it can be shown that an error has occurred in the sample collection or analysis phases of the study. Very often outliers provide much information to the study evaluators. Statistical tests such as the Dixon test exist to determine the presence of outliers (Dixon, 1950, 1951, 1953, 1960).

5.1.2.1. Evaluation of Analytical Methods

Analytical methods are evaluated in order to develop a data set based on validated analytical methods and appropriate QA/QC procedures. In a larger sense, analytical methods can be evaluated to determine the strength of the inferences made from them, and in turn, the confidence in the exposure assessment itself. Consequently, it is just as important to evaluate analytical methods used for data generated under another study as it is to evaluate the methods used to generate new data.

The EPA has established extensive QA/QC procedures (U.S. EPA, 1980). Before measurement data are used in the assessment, they should be evaluated against these procedures and the results stated. If this is not possible, the assessor must consider what effect the unknown quality of the data has on the confidence placed on the inferences and conclusions of the assessment.

5.1.2.2. Evaluation of Analytical Data Reports

An assortment of qualifiers is often used in data validation. These qualifiers are used to indicate QA/QC problems such as uncertain chemical identity or difficulty in determining chemical concentration. Qualifiers usually appear on a laboratory analysis report as a letter of the alphabet next to the analytical result. Some examples of data qualifiers, applied by U.S. EPA regional reviewers for Contract Laboratory Program (CLP) data include:

B (blank)—the analyte was found in blank samples;

J (judgment)—the compound is present but the concentration value is estimated;

U (undetected)—the chemical was analyzed for but not detected at the detection limit;

R (reject)—the quality control indicates that the data are unusable.

The exposure assessor may contact the laboratory or the person who validated the data if the definitions of the qualifiers are unclear. Since the exposure assessment is only as good as the data supporting it, it is essential to interpret these types of data properly to avoid misrepresenting the data set or biasing the results.

5.1.2.2.1. Evaluation of Censored Data Sets

Exposure assessors commonly encounter data sets containing values that are lower than limits deemed reliable enough to report as numerical values (i.e., quantification limits [QL]). These data points are often reported as nondetected and are referred to as censored. The level of censoring is based on the confidence with which the analytical signal can be discerned from the noise. While the concentration may be highly uncertain for substances below the reporting limit, it does not necessarily mean that the concentration is zero. As a result the exposure assessor is often faced with the problem of having to estimate values for the censored data. Although a variety of techniques have been described in the literature, no one procedure is appropriate under all exposure assessment circumstances; thus, the exposure assessor will need to decide on the appropriate method for a given situation. Techniques for analyzing censored data sets can be grouped into three classes (Helsel, 1990): Simple substitution methods, distributional methods, and robust methods.

Simple substitution methods, the most commonly encountered technique,

involve substitution of a single value as a proxy for each nondetected data value. Frequently used values have included zero, the QL, QL/2, and $QL/\sqrt{2}$.²⁶

In the worst-case approach, all nondetects are assigned the value of the QL, which is the lowest level at which a chemical may be accurately and reproducibly quantitated. This approach biases the mean upward. On the other hand, assigning all nondetects the value of zero biases the mean downward. The degree to which the results are biased will depend on the relative number of detects and nondetects in the data set and the difference between the reporting limit and the measured values above it.

In an effort to minimize the obvious bias introduced by choosing either zero or the QL as the proxy, two other values have been suggested, i.e., QL/2 and $QL/\sqrt{2}$. Assigning all nondetects as QL/2 (Nehls and Akland, 1973) assumes that all values between the QL and zero are equally likely; therefore, an average value would result if many samples in this range were measured. Hornung and Reed (1990) discuss the merits of assigning a value of $QL/\sqrt{2}$ for nondetects rather than QL/2 if the data are not highly skewed (geometric standard deviation < 3.0); otherwise they suggest using QL/2.

Based on reported analyses of simulated data sets that have been censored to varying degrees (Gleit, 1985; Hornung and Reed, 1990; Gilliom and Helsel, 1988; Helsel and Cohn, 1988), it can be concluded that substitution with QL/2 or $QL/\sqrt{2}$ for nondetects will be adequate for most exposure assessments provided that the nondetects do not exceed 10% to 15% of the data set or the data are not highly skewed. When such situations arise, the additional effort to make use of more sophisticated methods as discussed below is recommended. On the other hand, the exposure assessor may encounter situations in which the purpose of the assessment is only to serve as a screen to determine if a health concern has been triggered or if a more detailed study is required, then assigning the value of the QL to all nondetect values can be justified. If, when using this conservative approach, no concern is indicated, then no further effort is warranted. This method cannot be used to prove an unacceptable risk exists, and any exposure values calculated using this method should be caveated and clearly presented as "less than" estimates.

Distributional methods, unlike simple substitution methods, make use of the data above the reporting limit to extrapolate below it. One such technique is the use of log-probit analysis. This approach assumes a lognormal probability distribution of the data. In the probit analysis, the detected values are plotted on the scale and the nondetectable values are treated as unknowns, but their percentages are accounted for. The geometric mean is determined from the 50th percentile. As discussed by Travis and Land (1990), limitations of the method have been pointed out, but it is less biased and more accurate than the frequently used substitution methods. This method is useful in situations where the data set contains enough data points above the reporting limit to define the distribution function for the exposure values (i.e., lognormal) with an acceptable degree of confidence. The treatment of the nondetectable samples is then straightforward, assuming the nondetectable samples follow the same distribution as those above the reporting limit.

Robust methods have an advantage over distributional methods in so far as they do not assume that the data above the reporting limit follow a defined distribution (e.g., lognormal) and they are not subject to transformation bias in going from logarithms back to original units. Gilliom and Helsel (1988) have described the application of several approaches to data sets of varying sample size and degree of censoring. These methods involve somewhat more data manipulation than the log-probit method discussed earlier in this Section, but they may be more appropriate to use when the observed data do not fit a lognormal distribution. Generally, these methods only assume a distributional form for the censored values rather than the entire data set, and extrapolation from the uncensored data is done by using regression techniques.

In summary, when dealing with censored data sets, a variety of approaches can be used by the exposure assessor. Selecting the appropriate method requires consideration of the degree of censoring, the goals of the exposure assessment, and the accuracy required. Regardless of the method selected, the assessor should explain the choice made and how it may affect the summary statistics. Presenting only the summary statistics developed by one of these methods should be avoided. It is always useful to include a characterization of the data by the percentage of detects and nondetects in language such as "in 37% of the samples

the chemical was detected above the quantitation limit; of these 37%, the mean concentration was 47 ppm, the standard deviation was 5 ppm, etc."

5.1.2.2.2. Blanks and Recovery

Blank samples should be compared with the results from their corresponding samples. When comparing blank samples to the data set, the following rules should be followed (outlined in section 3):

- Sample results should be reported only if the concentrations in the sample exceed 10 times the maximum amount detected in the blank for common laboratory contaminants. Common laboratory contaminants include: acetone, 2-butanone (or methyl ethyl ketone), methylene chloride, toluene, and phthalate esters.
- Sample results should be reported only if the concentrations in the sample exceed 5 times the maximum amount detected in a blank for chemicals that are not common laboratory contaminants.

In general, for other types of qualifiers, the exposure assessor may include the data with qualifiers if they indicate that a chemical's concentration is uncertain, but its identity is known. If possible, the uncertainties associated with the qualifier should be noted.

Chemical spike samples that show abnormally high or low recoveries may result in qualified or rejected data. Assessors should not use rejected data; these samples should be treated as if the samples were not taken, since the resulting data are unreliable. Typically, analytical results are reported from the laboratory unadjusted for recovery, with the recovery percentage also reported. The assessor must determine how these data should be used to calculate exposures. If recovery is near 100%, concentrations are not normally adjusted (although the implicit assumption of 100% recovery should be mentioned in the uncertainty section). However, the assessor may need to adjust the data to account for consistent, but abnormally high or low recovery. The rationale for such adjustments should be clearly explained; individual program offices may develop guidance on the acceptable percent recovery limits before data adjustment or rejection is necessary.

5.1.3. Combining Measurement Data Sets from Various Studies

Combining data from several sources into a single data set must be done cautiously. The circumstances under which each set of data was collected (target population, sampling design,

²⁶ Some programs, such as the U.S. Department of Energy (1991), do not recommend this procedure at all, if it can be avoided.

location, time, etc.) and quality (precision, accuracy, representativeness, completeness, etc.) must be evaluated. Combining summary statistics of the data sets (e.g., means) into a single set may be more appropriate than combining the original values. Statistical methods are available for combining results from individual statistical tests. For example, it is sometimes possible to use several studies with marginally significant results to justify an overall conclusion of a statistically significant effect.

The best way to report data is to provide sufficient background information to explain what was done and why, including clear documentation of the source of the data and including any references.

5.1.4. Combining Measurement Data and Modeling Results

Combining model results with measurement data must be done with an understanding of how this affects the resulting inferences, conclusions, or exposure estimates. If model results are used in lieu of additional data points, they must be evaluated for accuracy and representativeness as if they were additional data, and the uncertainty associated with this data combination must be described fully, as discussed in section 5.1.3.

On the other hand, measurement data are often used within the context of the model itself, as calibration and verification points, or as a check on the plausibility of the model results. If measurements are used within the model, the uncertainty in these measurements affects the uncertainty of the model results, and should be discussed as part of the uncertainty of the model results.

5.2. Dealing With Data Gaps

Even after supplementing existing measurement data with model results, there are likely to be gaps in the information base to be used for calculating exposures and doses. There are several ways to deal with data gaps. None are entirely satisfactory in all situations, but they can be useful depending on the purposes of the assessment and the resources available. The following options can be used singly or in combination:

- New data can be collected. This may be beyond the reach of the assessor's resources, but promises the best chance for getting an accurate answer. It is most likely to be a useful option if the new data are quick and easy to obtain.
- The scope of the assessment can be narrowed. This is possible if the data

gaps are in one pathway or exposure route, and the others have adequate data. It may be a viable option if the pathway or route has values below certain bounds, and those bounds are small relative to the other pathways being evaluated. This is unlikely to be satisfactory if the part of the assessment deleted is an important exposure pathway or route and must be evaluated.

- Conservative²⁷ assumptions can be used. This option is useful for establishing bounds on exposure parameters, but limits how the resulting exposures and doses can be expressed. For example, if one were to assume that a person stays at home 24 hours a day as a conservative assumption, and used this value in calculations, the resulting contact time would have to be expressed as an upper limit rather than a best estimate. When making conservative assumptions, the assessor must be aware of (and explain) how many of these are made in the assessment, and how they influence the final conclusions of the assessment.²⁸

- Models may be used in some cases, not only to estimate values for concentrations or exposures, but also to check on how conservative certain assumptions are.

- Surrogate data may also be used in some cases. For example, for pesticide applicators' exposure to pesticides, the EPA Office of Pesticide Programs (U.S. EPA, 1987d) assumes that the general parameters of application (such as the human activity that leads to exposure) are more important than the properties of the pesticide in determining the level of exposure.²⁹ This option assumes that surrogate data are available and that the differences between the chemical and the surrogate are small. If a clear relationship can be determined between the concentration of a chemical and the surrogate (usually termed an indicator chemical) in a medium, this relationship could also be used to fill data gaps. In any case, the strength and character of the relationship between the chemical and the surrogate must be explained.

²⁷ "Conservative" assumptions are those which tend to maximize estimates of exposure or dose, such as choosing a value near the high end of the concentration or intake rate range.

²⁸ Obviously, the mathematical product of several conservative assumptions is more conservative than any single assumption alone. Ultimately, this could lead to unrealistically conservative bounding estimates (see section 5.3).

²⁹ Note that when using a passive dosimetry monitoring method, what is measured is the amount of chemical impinging on the skin surface or available for inhalation, that is, exposure, not the actual dose received. Factors such as dermal penetration, are, of course, expected to be highly chemical dependent.

- Professional judgment can be used. The utility of this option depends on the confidence placed in the estimate. Expert opinion based on years of observation of similar circumstances usually carries more weight than anecdotal information. The assessor must discuss the implications of these estimates in the uncertainty analysis.

5.3. Calculating Exposure and Dose

Depending on the approach used to quantify exposure and dose, various types of data will have been assembled. In calculating exposures and doses from these data, the assessor needs to direct attention specifically to certain aspects of the data. These aspects include the use of short-term data for long-term projections, the role of personal monitoring data, and the particular way the data might be used to construct scenarios. Each of these aspects is covered in turn below.

5.3.1. Short-Term Versus Long-Term Data for Population Exposures

Short-term data, for the purposes of this discussion, are data representing a short period of time measured (or modeled) relative to the time period covered in the exposure assessment. For example, a 3-day sampling period would produce short-term data if the exposure assessment covered a period of several years to a lifetime. The same 3-day sampling period would not be considered short-term if the assessment covered, say, a few days to a week.

Short-term data can provide a snapshot of concentrations or exposures during that time, and an inference must be made about what that means for the longer term if the exposure assessment covers a long period. The assessor must determine how well the short-term data represent the longer period.

Even when short-term population data are statistically representative (i.e., they describe the shape of the distribution, the mean, and other statistics), use of these short-term data to infer long-term exposures and risks must be done with caution. Using short-term data to estimate long-term exposures has a tendency to underestimate the number of people exposed, but to overestimate the exposure levels to the upper end of the distribution, even though the mean will remain the same.³⁰ Both

³⁰ Consider, for example, a hypothetical set of 100 rooms (microenvironments) where the concentration of a particular pollutant is zero in 50 of them, and ranges stepwise from 1 to 50 (nominal concentration units) in the remainder. If one person were in each room, short-term "snapshot" monitoring would show that 50 people were

concentration variation at a single point and population mobility will drive the estimates of the levels of exposure for the upper tail of the distribution toward the mean. If short-term data are used for long-term exposure or dose estimates, the implications of this on the estimated exposures must be discussed in the assessment. Likewise, use of long-term monitoring data for specific short-term assessments can miss significant variations due to short-term conditions or activities. Long-term data should be used cautiously when estimating short-term exposures or doses, and the implications should be discussed in the assessment.

5.3.2. Using Point-of-Contact Data to Calculate Exposure and Dose

Point-of-contact exposure assessments are often done with the intent of protecting the individuals, often in an occupational setting. When exposures are being evaluated to determine whether they exceed an action level or other benchmark, point-of-contact measurements are the most relevant data.

Typically, point-of-contact measurement data reflect exposures over periods of minutes to perhaps a week or so. For individuals whose exposures have been measured, these data may be used directly as an indication of their exposure during the sampling period, provided they are of adequate quality, measure the appropriate chemical, and actually measure exposure while it occurs. This is the only case in which measurement data may be used directly as exposure data.

When using point-of-contact measurements, even with statistically based data, several inferences still must be made to calculate exposure or dose:

- Inferences must be made to apply short-term measurements of exposure to long-term estimates of exposure; these are subject to the cautions outlined in section 5.3.1.
- Inferences must be made about the representativeness of the individual or persons sampled for the individual or

unexposed and the others were exposed to concentrations ranging from 1 to 50. If the concentration in each room remained constant and people were allowed to visit any room at random, long-term monitoring would indicate that all 100 were exposed to a mean concentration of 12.75. The short-term data would tend to overestimate concentration and underestimate the number of persons exposed if applied to long-term exposures. If only average values were available, the long-term data would tend to underestimate concentration and overestimate the number exposed if applied to short-term exposures. Because populations are not randomly mobile or static, the exposure assessor should determine what effect this has on the exposure estimate.

population segment for which the assessment is done.

- Inferences must be made about the factors converting measured exposure to potential or internal dose for use in a risk assessment.

- If the assessment requires it, inferences must be made about the relationship between the measured chemical exposures and the presence and relative contribution of various sources of the chemical.

5.3.3. The Role of Exposure Scenarios in Exposure Assessment

Exposure scenarios have several functions in exposure and risk assessments. First, they are calculational tools to help the assessor develop estimates of exposure, dose, and risk. Whatever combination of data and models is used, the scenario will help the assessor to picture how the exposure is taking place, and will help organize the data and calculations. Second, the estimates derived from scenarios are used to develop a series of exposure and risk descriptors, which were discussed in section 2.3. Finally, exposure scenarios can often help risk managers make estimates of the potential impact of possible control actions. This is usually done by changing the assumptions in the exposure scenario to the conditions as they would exist after the contemplated action is implemented, and reassessing the exposure and risk. These three uses of exposure assessments are explained in sections 5.3.3.1, 5.3.3.2, and 5.3.3.3, respectively.

An exposure scenario is the set of information about how exposure takes place. An exposure scenario generally includes facts, data, assumptions, inferences, and sometimes professional judgment about the following:

- The physical setting where exposure takes place (exposure setting)
- The exposure pathway(s) from source(s) to exposed individual(s) (exposure pathways)
- The characterization of the chemical, i.e., amounts, locations, time variation of concentrations, source strength, environmental pathways from source to exposed individuals, fate of the chemical in the environment, etc. (characterization of the chemical)
- Identification of the individual(s) or population(s) exposed, and the profile of contact with the chemical based on behavior, location as a function of time, characteristics of the individuals, etc. (characterization of the exposed population)

- If the dose is to be estimated, assumptions about the transfer of the

chemical across the boundary, i.e., ingestion rates, respiration rates, absorption rates, etc. (intake and uptake rates)

It usually is necessary to know whether the effect of concern is chronic, acute, or dependent on a particular exposure time pattern.

The risk characterization, the link between the development of the assessment and the use of the assessment, is usually communicated in part to the risk manager by means of a series of "risk descriptors," which are merely different ways to describe the risk. Section 2.3 outlined two broad types of descriptors: individual risk descriptors and population risk descriptors, with several variations for each. To the exposure or risk assessor, different types of risk information require different risk descriptors and different analyses of the data. The following paragraphs discuss some of the aspects of developing and using exposure scenarios in various functions for exposure assessment.

5.3.3.1. Scenarios as a Means to Quantify Exposure and Dose

When using exposure scenario evaluation as a means to quantify exposure and dose, it is possible to accumulate a large volume of data and estimated values, and both the amount and type of information can vary widely. The exposure scenario also contains the information needed to calculate exposure, since the last three bullets above (section 5.3.3) are the primary variables in most exposure and dose equations.

As an example, consider Equation 2-5, the equation for lifetime average daily potential dose ($LADD_{pot}$). This equation uses the variables of exposure concentration (C), intake rate (IR), and exposure duration (ED) as the three primary variables. Body weight (BW) and averaging time (AT) (in this case, lifetime, LT) are not related to the exposure or dose *per se*, but are averaging variables used to put the resulting dose in convenient units of lifetime average exposure or dose per kg of body weight.

In looking at the three primary variables (C, IR, and ED), the exposure assessor must determine what value to use for each to solve the equation. In actuality, the information available for a variable like C may consist of measurements of various points in an environmental medium, source and fate characterizations, and model results. There will be uncertainty in the values for C for any individual; there will also be variability among individuals. Each

of these primary variables will be represented by a range of values, even though at times, the boundaries of this range will be unknown. How exposure or dose is calculated depends on how these ranges are treated.

In dealing with these ranges in trying to solve the equation for LADD, the assessor has at least two choices. First, statistical tools, such as the Monte Carlo analysis, can be used to enter the values as frequency distributions, which results in a frequency distribution for the LADD. This is an appropriate strategy when the frequency distributions are known for C, IR, and ED (or for the uptake analogs, C, K_p, SA, and ED introduced in section 2), and when these variables are independent.

A second approach is to select or estimate discrete values from the ranges of each of the variables and use these values to solve the LADD equation. This approach usually results in a less certain estimate, but may be easier to do. Which values are used determines how the resulting estimate will be described. Several terms for describing such estimates are discussed in section 5.3.3.2.

Since exposure to chemicals occurs through a variety of different pathways, contact patterns, and settings, sufficient perspective must be provided to the users of the assessment (usually risk managers) to help them make an informed decision. Providing this perspective and insight would be relatively straightforward if complete and accurate information were known about the exposure, dose, and risk for each and every person within the population of interest. In this hypothetical situation, these individual data could actually be arrayed next to the name of each person in the population, or the data could be compiled into frequency distribution curves. From such distributions, the average, median, maximum, or other statistical values could easily be read off the curves and presented to the risk manager. In addition, accurate information could be provided about how many persons are above certain exposure, dose, or risk levels as well as information about where various subgroups fall within the subject distribution.

Unfortunately, an assessor rarely has these kinds of data; the reality an assessor faces usually falls far short of this ideal. But it is precisely this kind of information about the distribution of exposure, dose, and risk that is needed many times by the risk assessor to characterize risk, and by the risk manager to deal with risk-related issues.

In the absence of comprehensive data, or if the scenario being evaluated is a possible future use or post-control scenario, an assessor must make assumptions in order to estimate what the distribution would look like if better data were available, or if the possible future use becomes a reality. Communicating this estimated distribution to the risk manager can be difficult. The assessor must not only estimate exposure, dose, and risk levels, but must also estimate where those levels might fall on the actual distributions or estimated distributions for potential future situations. To help communicate where on the distribution the estimate might fall, loosely defined terms such as reasonable worst case, worst case, and maximally exposed individual have been used by assessors. Although these terms have been used to help describe the exposure assessor's perceptions of where estimated exposures fall on the actual or potential distribution for the future use, the *ad hoc* nature of the historical definitions used has led to some inconsistency. One of the goals of these Guidelines is to promote greater consistency in the use of terms describing exposure and risk.

5.3.3.2. Exposure Scenarios and Exposure Estimators as Input to Risk Descriptors

As discussed in section 2.3, risk descriptors convey information about risk to users of that information, primarily risk managers. This information usually takes the form of answers to a relatively short set of questions, not all of which are applicable to all assessments. Section 5.3.5 provides more detail on how the exposure assessor's analysis leads to construction of the risk descriptors.

5.3.3.3. Exposure Scenarios as a Tool for Option Evaluation

A third important use for exposure scenarios is as a tool for evaluating proposed options for action. Risk managers often have a number of choices for dealing with environmental problems, from taking no action on one extreme to a number of different actions, each with different costs, on the other. Often the exposure scenarios developed as part of the baseline risk assessment provide a powerful tool to evaluate the potential reduction of exposure and risk for these various options, and consequently are quite useful in many cost-benefit analyses.

There are several additional related uses of exposure scenarios for risk managers. They may help establish a range of options for cleanup by showing the sensitivity of the risk estimates to the changes in assumed source or

exposure levels. The exposure assessor can use the sensitivity analysis of the exposure scenario to help evaluate and communicate the uncertainty of the assumptions, and what can be done to reduce that uncertainty. Well-crafted and soundly based exposure scenarios may also help communicate risks and possible options to community groups.

Although it is beyond the scope of these Guidelines to detail the methods used for option evaluation and selection, the assessor should be aware of this potential use. Discussing strategy (and specific information needs) with risk managers is usually prudent before large resource expenditures are made in the risk assessment area.

5.3.4. General Methods for Estimating Exposure and Dose

A variety of methods are used to obtain estimates of dose necessary for risk characterization. These range from quick screening level calculations and rules of thumb to more sophisticated techniques. The technique to be used in a given case is a matter of the amount of information available and the purpose of the assessment. Several of the methods are outlined in the following sections.

Normally it is neither practical nor advisable to immediately develop detailed information on all the potential pathways, since not all may contribute significantly to the outcome of the assessment.³¹ Rather, evaluation of the scenario is done in an iterative manner. First, screening or bounding techniques are used to ascertain which pathways are unimportant, then the information for the remaining pathways is refined, iteratively becoming more accurate, until the quantitative objectives of the assessment are met (or resources are depleted).

In beginning the evaluation phase of any assessment, the assessor should have a scenario's basic assumptions (setting, scope, etc.) well identified, one or more applicable exposure pathways defined, an equation for evaluating the exposure or dose for each of those exposure pathways, and the data and information requirements pertinent to solving the equations. Quality and quantity of data and information needed to substitute quantitative values or

³¹ There are some important exceptions to this statement. First, the public or other concerned groups may express particular interest in certain pathways, which will not normally be dropped entirely at this point. Second, for routine repetitive assessments using a certain standard scenario for many chemicals, once the general bounding has been done on the various possible pathways, it may become standard operating procedure to immediately begin developing information for particular pathways as new chemicals are assessed.

ranges into the parameters of the exposure equation will often vary widely, from postulated assumptions to actual high-quality measurements. Many times, there are several exposure pathways identified within the scenario, and the quality of the data and information may vary for each.

A common approach to estimating exposure and dose is to do a preliminary evaluation, or screening step, during which bounding estimates are used, and then to proceed to refine the estimates for those pathways that cannot be eliminated as of trivial importance.

5.3.4.1. Preliminary Evaluation and Bounding Estimates

The first step that experienced assessors usually take in evaluating the scenario involves making bounding estimates for the individual exposure pathways. The purpose of this is to eliminate further work on refining estimates for pathways that are clearly not important.

The method used for bounding estimates is to postulate a set of values for the parameters in the exposure or dose equation that will result in an exposure or dose higher than any exposure or dose expected to occur in the actual population. The estimate of exposure or dose calculated by this method is clearly outside of (and higher than) the distribution of actual exposures or doses. If the value of this bounding estimate is not significant, the pathway can be eliminated from further refinement.³²

The theoretical upper bounding estimate (TUBE) is a type of bounding estimate that can be easily calculated and is designed to estimate exposure, dose, and risk levels that are expected to exceed the levels experienced by all individuals in the actual distribution. The TUBE is calculated by assuming limits for all the variables used to calculate exposure and dose that, when combined, will result in the mathematically highest exposure or dose (highest concentration, highest intake rate, lowest body weight, etc.). The theoretical upper bound is a bounding estimate that should, if the limits of the parameters used are known, ensure that the estimate is above the actual exposures received by all

individuals in the population. It is not necessary to go to the formality of the TUBE to assure that the exposure or dose calculated is above the actual distribution, however, since any combination that results in a value clearly higher than the actual distribution can serve as a suitable upper bound.

The bounding estimate (a limit of individual exposure, dose or risk) is most often used only to eliminate pathways from further consideration. This is often done in screening-level assessments, where bounding estimates of exposure, dose, or risk provide a quick and relatively easy check on whether the levels to be assessed are trivial relative to a level that would cause concern. If acceptably lower than the concern level, then additional assessment work is not necessary.

Bounding estimates also are used in other types of assessments. They can be used for deregulation of chemicals when pathways or concentrations can be shown to present insignificant or *de minimis* risk. They can be used to determine whether more information is needed to determine whether a pathway is significant; if the pathway's significance cannot be ruled out by a bounding estimate, test data may be needed to refine the estimate.

There are two important points about bounding estimates. First, the only thing the bounding estimate can establish is a level to eliminate pathways from further consideration. It cannot be used to make a determination that a pathway is significant (that can only be done after more information is obtained and a refinement of the estimate is made), and it certainly cannot be used for an estimate of actual exposure (since by definition it is clearly outside the actual distribution). Second, when an exposure scenario is presented in an assessment, it is likely that the amount of refinement of the data, information, and estimates will vary by pathway, some having been eliminated by bounding estimates, some eliminated after further refinement, and others fully developed and quantified. This is an efficient way to evaluate scenarios. In such cases, bounding estimates must not be considered to be equally as sophisticated as an estimate of a fully developed pathway, and should not be described as such.

Experienced assessors can often eliminate some obvious pathways more or less by inspection as they may have evaluated these pathways many times before.³³ In these cases, the assessor

must still explain why the pathway is being eliminated. For less experienced assessors, developing bounding estimates for all pathways is instructive and will be easier to defend.

5.3.4.2. Refining the Estimates of Exposure and Dose

For those pathways not eliminated by bounding estimates or judged trivial, the assessor will then evaluate the resulting exposure or dose. At this point, the assessor will make estimates of exposure or dose that are designed to fall on the actual distribution. The important point here is that unlike a bounding estimate, these estimates of exposure or dose should focus on points in the actual distribution. Both estimates of central tendency and estimates of the upper end of the distribution curve are useful in crafting risk descriptors.

Consider Equation 2-6 for the lifetime average daily potential dose ($LADD_{pot}$), an equation often used for linear, nonthreshold carcinogen risk models. The assessor will use the data, ranges of data, distributions of data, and assumptions about each of the factors needed to solve the equation for dose. Generally, both central estimates and high-end estimates are performed. Each of these estimates has uncertainty (perhaps unquantifiable uncertainty), and the better the quality and comprehensiveness of data used as input to the equation, the less uncertainty.

After solving the equation, the assessor will determine whether the uncertainty associated with the answer is sufficiently narrow to allow the risk descriptors to be developed (see section 3.4) and to answer satisfactorily the questions posed in the exposure assessment statement of purpose. Evaluating whether the data, uncertainty, risk descriptors, and answers to the questions are good enough is usually a joint responsibility of the risk assessor and the risk manager.

Should the estimates of exposure or dose have sufficiently narrow uncertainty, the assessor can then proceed to develop the descriptors and finish the assessment. If not, the data or assumptions used usually will have to be refined, if resources allow, in an attempt to bring the estimated exposure or dose closer to what the assessor believes are the actual values in the population. Refining the estimates usually requires that new data be brought into consideration³⁴; this new

³² "Not significant" can mean either that it is so small relative to other pathways that it will not add perceptibly to the total exposure being evaluated or that it falls so far below a level of concern that even when added to other results from other pathways, it will be trivial. Note that a "level of concern" is a risk management term, and the assessor must discuss and establish any such levels of concern with risk managers (and in some cases, concerned groups such as the local community) before eliminating pathways as not significant.

³³ Experienced assessors may also be able to determine quickly that a pathway requires refined estimation.

³⁴ It also can involve new methods or additional methods for analyzing the old data.

information can be other studies from the literature, information previously developed for another, related purpose that can be adapted, or new survey, laboratory, or field data. The decision about which particular parts of the information base to refine should be based both on which data will most significantly reduce the uncertainty of the overall exposure or dose estimate, and on which data are in fact obtainable either technologically or within resource constraints.

After refinement of the estimate, the assessor and risk manager again determine whether the estimates provided will be sufficient to answer the questions posed to an acceptable degree, given the uncertainties that may be associated with those estimates. Refinements proceed iteratively until the assessment provides an adequate answer within the resources available.

5.3.5. Using Estimates for Developing Descriptors

Risk assessors and risk managers are encouraged to explore a range of ways to describe exposure and risk information, depending on the purpose of the assessment and the questions for which the risk manager must have answers. Section 2.3 outlines a series of risk descriptors; in the sections below, these are discussed in the context of how an exposure assessor's analysis of the data would lead to various descriptors for risk.

5.3.5.1. Individual Exposure, Dose, and Risk

Questions about individual risk are an important component of any assessment, especially an estimate of the high end of the distribution. Section 5.3.4.1 indicated that bounding estimates are actually a useful but limited form of individual risk estimate, a form which is by definition beyond the highest point on the population distribution. This section deals with estimates that are actually on the distribution of exposure, dose, or risk.

There are several approaches for arriving at an individual risk estimate. Since calculation of risk involves using information from fields other than exposure assessment, the reader is advised to consult other Agency guidelines for more detailed discussions (e.g., U.S. EPA, 1986b, 1986c, 1988b, 1988c, 1991a). The uncertainty in the risk estimate will depend heavily on the quality of the information used. There are several steps in the process:

First, the question of unusual susceptibility of part of the population must be addressed. If equal doses result in widely different responses in two

individuals, it may be necessary to consult with scientists familiar with the derivation of the dose-response relationship for the chemical in question in order to ascertain whether this is normal variability among members of a population. Normal variability should have been considered as part of the development of the dose-response relationship; unusual susceptibility may not have been. If such a highly susceptible subgroup can be identified, it is often useful to assess their risk separately from the general population. It will not be common, given the current data availability, to clearly identify such susceptible subgroups. If none can be identified, the default has usually been to assume the dose-response relationship applies to all members of the population being assessed. Where no information shows the contrary, this assumption may be used provided it is highlighted as a source of uncertainty.

Second, after the population or population segment can be represented by a single dose-response relationship, the appropriate dose for use in the dose-response relationship (absorbed/internal dose, potential dose, applied dose, effective dose) must be identified. For dose-response relationships based on administered dose in animal studies, potential dose will usually be the human analogue. If the dose-response relationship is based on internal dose, then that is the most appropriate human dose. If the estimates of exposure and dose from the exposure assessment are in an inappropriate form (say, potential dose rather than internal dose), they must be converted before they are used for risk calculations. This may involve analysis of bioavailability, absorption rates as a function of form of the chemical and route, etc. If these data are not available, the default has been to assume the entire potential dose becomes the internal dose.³⁵ As more data become available concerning absorption for different chemicals, this conservative assumption may not always be the best, or even a credible, default. Whatever assumption is made

concerning absorption (or the relationships among any of the different dose terms if used, for that matter), it should be highlighted in the uncertainty section.

Once the first two steps have been done, and the dose-response relationship and type of dose have been identified, the exposure and dose information needs to be put in the appropriate form. Ideally, this would be a distribution of doses of the appropriate type across the population or population subgroup of interest. This may involve converting exposures into potential doses or converting potential doses into internal, delivered, or biologically effective doses. Once this is accomplished, the high-end estimate of dose will often (but not always) lead fairly directly to the high-end estimate of risk. The method used to develop the high-end estimate for dose depends on the data available. Because of the skewed nature of exposure data, there is no exact formula that will guarantee an estimate will fall into this range in the actual population if only sparse data are available.

The high-end risk is a plausible estimate of the individual risk for those persons at the upper end of the risk distribution. The intent of this descriptor is to convey an estimate of risk in the upper range of the distribution, but to avoid estimates that are beyond the true distribution. Conceptually, high-end risk means risks above the 90th percentile of the population distribution, but not higher than the individual in the population who has the highest risk. This descriptor is intended to estimate the risks that are expected to occur in small but definable high-end segments of the subject population. The use of "above the 90th percentile" in the definition is not meant to precisely define the range of this descriptor, but rather to clarify what is meant conceptually by high end.

The high-end segments of the exposure, dose, and risk populations may represent different individuals. Since the location of individuals on the exposure, dose, and risk distributions may vary depending on the distributions of bioavailability, absorption, intake rates, susceptibility, and other variables, a high exposure does not necessarily result in a high dose or risk, although logically one would expect a moderate to highly positive correlation among exposure, dose, and risk.

When the complete data on the population distributions of exposures and doses are available, and the significance of the factors above (bioavailability, etc.) are known to the

³⁵ The unstated assumption is often made that the relationship between administered dose and absorbed dose in the animal is the same as that between potential dose and internal dose in humans, provided a correction is made for body weight/surface area. In other words, the bioavailability and absorption fractions are assumed to be the same in the human as in the animal experiment. If no correction is made for absorption, this leads to the assumption that the absorption percent is the same as in the animal experiment from which the dose-response relationship was derived. Note this uncorrected conversion of potential dose to internal dose does not assume "100% absorption" unless there was 100% absorption in the animal study.

extent to allow a risk distribution to be constructed, the high-end risk estimate can be represented by reporting risks at selected percentiles of the distributions, such as the 90th, 95th, or 98th percentile. When the complete distributions are not available, the assessor should conceptually target something above the 90th percentile on the actual distribution.

In developing estimates of high-end individual exposure and dose, the following conditions must be met:

- The estimated exposure or dose is on the expected distribution, not above the value one would expect for the person with the highest estimated risk in the population. This means that when constructing this estimate from a series of factors (environmental concentrations, intake rates, individual activities, etc.), not all factors should be set to values that maximize exposure or dose, since this will almost always lead to an estimate that is much too conservative.

- The combination of values assigned to the exposure and dose factors can be expected to be found in the actual population. In estimating high-end exposures or doses for future use or post-control scenarios, the criterion to be used should be that it is expected to be on the distribution provided the future use or control measure occurs.³⁶

Some of the alternative methods for determining a high-end estimate of dose are:

- If sufficient data on the distribution of doses are available, take the value directly for the percentile(s) of interest within the high end. If possible, the actual percentile(s) should be stated, or the number of persons determined in the high end above the estimate, in order to give the risk manager an idea of where within the high end-range the estimate falls.

- If data on the distribution of doses are not available, but data on the parameters used to calculate the dose are available, a simulation (such as an exposure model or Monte Carlo simulation) can sometimes be made of the distribution. In this case, the assessor may take the estimate from the simulated distribution. As in the method above, the risk manager should be told where in the high-end range the estimate falls by stating the percentile or the number of persons above this estimate.

The assessor and risk manager should be cautioned that unless a great deal is known about exposures or doses at the high end of the distribution, simulated distributions may not be able to differentiate between bounding estimates and high-end estimates. Simulations often include low-probability estimates at the upper end that are higher than those actually experienced in a given population, due to improbability of finding these exposures or doses in a specific population of limited size, or due to nonobvious correlations among

parameters at the high ends of their ranges.³⁷ Using the highest estimate from a Monte Carlo simulation may therefore overestimate the exposure or dose for a specific population, and it is advisable to use values somewhat less than the highest Monte Carlo estimated value if one is to defend the estimate as being within the actual population distribution and not above it.

Simulations using finite ranges for parameters will result in a simulated distribution with a calculable finite maximum exposure, and the maximum exposures calculated in repeated simulations will not exceed this theoretical maximum.³⁸ When unbounded default distributions, such as lognormal distributions, are used for input parameters to generate the simulated exposure distributions, there will not be a finite maximum exposure limit for the simulation, so the maximum value of the resulting simulated distribution will vary with repeated simulations. The EPA's Science Advisory Board [SAB] (U.S. EPA, 1992a) has recommended that values above a certain percentile in these simulations be treated as if they were bounding estimates, not estimates of high-end exposures (see Figure 5-1). The SAB noted that for large populations, simulated exposures, doses, and risks above the 99.9th percentile may not be meaningful when unbounded lognormal distributions are used as a default.

³⁶ This means that estimates of high-end exposure or dose for future uses are limited to the same conceptual range as current uses. Although a "worst-case" combination of future conditions or events may result in an exposure that is conceivably possible, the assessor should not merely use a worst-case combination as an estimate of high-end exposure for possible future uses. Rather, the assessor must use judgment as to what the range of exposures or doses would plausibly be,

given the population size and probability of certain events happening.

³⁷ For example, although concentration, frequency, duration, and breathing rate may be independent for a consumer painting rooms in a house under most normal circumstances, if the concentration is high enough, it may affect the other parameters such as duration or breathing rate. These types of high-end correlations are difficult to quantify, and techniques such as Monte Carlo simulations will not consider them unless

relationships are known and taken into account in the simulation. If extreme concentration in this case resulted in lower breathing rate or duration, a non-corrected Monte Carlo simulation could overestimate the exposure or dose at the high end. Far less likely, due to self-preservation processes, would seem the case where high concentration increases duration or intake rate, although this theoretically might also occur.

³⁸ This maximum is the theoretical upper bounding estimate (TUBE).

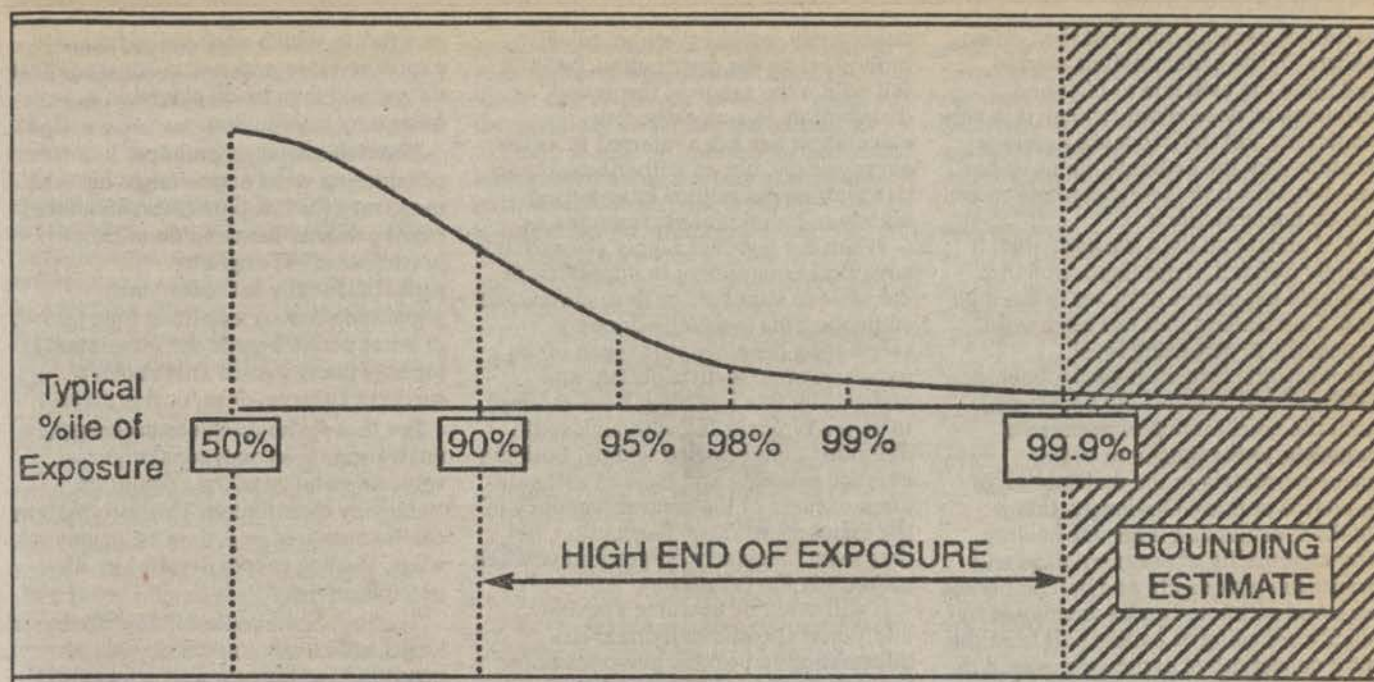


Figure 5-1. Schematic of exposure estimators for unbounded simulated population distributions.

For simulated distributions, whether derived from measured data or statistical methods such as Monte Carlo analysis, the high-end estimator should not exceed the 99.9th percentile. Bounding estimates should reflect the size of the population (see text), therefore bounding estimates for this type of distribution should not automatically be set at 99.9th percentile. Several statistical estimators of exposure should be identified, e.g., the 50th, 90th, or 95th percentiles. The distribution should reflect exposures, not just concentrations.

Although the Agency has not specifically set policy on this matter, exposure assessors should observe the following caution when using simulated distributions. The actual percentile cutoff above which a simulation should be considered a *bounding estimate* may be expected to vary depending on the size of the population. Since bounding estimates are established to develop statements that exposures, doses, and risks are "not greater than . . .," it is prudent that the percentile cutoff bound expected exposures for the size of the population being evaluated. For example, if there are 100 persons in the

population, it may be prudent to consider simulated exposures above the 1 in 500 level or 1 in 1000 level (i.e., above the 99.5th or 99.9th percentile, respectively) to be bounding estimates. Due to uncertainties in simulated distributions, assessors should be cautious about using estimates above the 99.9th percentile for estimates of *high-end* exposure regardless of the size of the population. The Agency or individual program offices may issue more direct policy for setting the exact cutoff value for use as high-end and bounding estimates in simulations.

- If some information on the distribution of the variables making up the exposure or dose equation (e.g., concentration, exposure duration, intake or uptake rates) is available, the assessor may estimate a value which falls into the high end by meeting the defining criteria of "high end": An estimate that will be within the distribution, but high enough so that less than 1 out of 10 in the distribution will be as high. The assessor often constructs such an estimate by using maximum or near-maximum values for one or more of the most sensitive

variables, leaving others at their mean values.³⁹ The exact method used to calculate the estimate of high-end exposure or dose is not critical; it is very important that the exposure assessor explain why the estimate, in his or her opinion, falls into the appropriate range, not above or below it.

If almost no data are available, it will be difficult, if not impossible, to estimate exposures or doses in the high end. One method that has been used, especially in screening-level assessments, is to start with a bounding estimate and back off the limits used until the combination of parameter values is, in the judgment of the assessor, clearly in the distribution of exposure or dose. Obviously, this method results in a large uncertainty. The availability of pertinent data will determine how easily and defensibly the high-end estimate can be developed by simply adjusting or backing off from the ultra conservative assumptions used in the bounding estimates. This estimate must still meet the defining criteria of "high end," and the assessor should be ready to explain why the estimate is thought to meet the defining criteria.

A descriptor of central tendency may be either the arithmetic mean risk (average estimate) or the median risk (median estimate), but should be clearly labeled as such. Where both the arithmetic mean and the median are available, but differ substantially, it is helpful to present both.

Exposure and dose profiles often fall in a skewed distribution that many times appears to be approximately lognormally distributed, although statistical tests for lognormality may fail. The arithmetic mean and the median are the same in a normal distribution, but exposure data are rarely normally distributed. As the typical skewness in the distribution increases, the exposure or dose distribution comes to resemble a lognormal curve where the arithmetic mean will be higher than the median. It is not unusual for the arithmetic mean to be located at the 75th percentile of the distribution or higher. Thus, the arithmetic mean is not necessarily a good indicator of the midpoint (median, 50th percentile) of a distribution.

The average estimate, used to describe the arithmetic mean, can be approximated by using average values for all the factors making up the exposure or dose equation. It does not

necessarily represent a particular individual on the distribution, but will fall within the range of the actual distribution. Historically, this calculation has been referred to as the average case, but as with other *ad hoc* descriptors, definitions have varied widely in individual assessments.

When the data are highly skewed, it is sometimes instructive to approximate the median exposure or dose, or median estimate. This is usually done by calculating the geometric mean of the exposure or dose distribution, and historically this has often been referred to as the typical case, although again, definitions have varied widely. Both the average estimate and median estimate are measures of the central tendency of the exposure or dose distribution, but they must be clearly differentiated when presenting the results.

It will often be useful to provide additional specific individual risk information to provide perspective for the risk manager. This specific information may take the form of answers to what if questions, such as, what if a consumer should use this product without adequate ventilation? For the risk manager, these questions are likely to put bounds on various aspects of the risk question. For the assessor, these are much less complicated problems than trying to estimate baseline exposure or dose in an actual population, since the answers to these questions involve choosing values for various parameters in the exposure or risk equations and solving them for the estimate.

This type of risk descriptor is a calculation of risk to specific hypothetical or actual combinations of factors postulated within the exposure assessment. It is often valuable to ask and answer specific questions of the "what if" nature to add perspective to the risk assessment.

Each assessment may have none, one, or several of these specific types of descriptors. The answers to these questions might be a point estimate or a range, but are usually fairly simple to calculate. The answers to these types of postulated questions, however, do not directly give information about how likely that combination of values might be in the actual population, so there are some limits to the applicability of these descriptors.

5.3.5.2. Population Exposure, Dose, and Risk

Questions about population exposure, dose, and risk are central to any risk assessment. Ideally, given the time and methods, the assessor might strive to construct a picture of exposure, dose,

and risk in which each individual exposure, dose and risk is known. These data could then be displayed in a frequency distribution.

The risk manager, perhaps considering what action might be necessary for this particular situation, might ask how many cases of the particular effect might be probabilistically estimated in a population during a specific time period, or what percentage of the population is (or how many people are) above a certain exposure, dose, or risk level.

For those who do the assessments, answering these questions requires some knowledge of the population frequency distribution. This information can be obtained or estimated in several ways, leading to two descriptors of population risk.

The first is the probabilistic number of health effect cases estimated in the population of interest over a specified time period. This descriptor can be obtained either by summing the individual risks over all the individuals in the population, or by multiplying the slope factor obtained from a carcinogen dose-response relationship, the arithmetic mean of the dose, and the size of the population. The latter approach may be used only if the risk model assumes a single linear, nonthreshold response to dose, and then only with some caution.⁴⁰ If risk varies

⁴⁰For example, when calculating risks using doses and "slope factors," the risk is approximately linear with dose until relatively high individual risks (about 10^{-3}) are attained, after which the relationship is no longer even approximately linear. This results from the fact that no matter how high the dose, the individual risk cannot exceed 1, and the dose-risk curve approaches 1 asymptotically. This can result in artifacts when calculating population risk from average individual doses and population size if there are individuals in the population in this nonlinear risk range. Consider a population of five persons, only one of whom is exposed. As an example, assume a lifetime average daily dose of 100 mg/kg/day corresponds to an individual risk of 4×10^{-4} . Increasing the dose fivefold, to 500 mg/kg/day, would result in a higher individual risk for that individual, but due to the nonlinearity of the dose-risk curve, not yet a risk of 1. The average dose for the five persons in the population would then be 100 mg/kg/day. Multiplying the "average risk" of 4×10^{-4} by the population size of five results in an estimate of two cases, even though in actuality only one person is exposed. Although calculating average individual dose, estimating individual risk from it, and multiplying by the population size is a useful approximation if all members of the population are within the approximately linear range of the dose-risk curve, this method should not be used if some members of the population have calculated individual risks higher than about 10^{-3} , since it will overestimate the number of cases.

³⁹Maximizing all variables, as is done in bounding estimates, will result in virtually all cases in an estimate that is above the bounds of this range, that is, above the actual values seen in the population.

linearly with dose, knowing the arithmetic mean risk and the population size can lead to an estimate of the extent of harm for the population as a whole, excluding sensitive subgroups for which a different dose-response curve may need to be used. For noncarcinogens, or for nonlinear, nonthreshold carcinogen models, using the arithmetic mean exposure or dose, multiplying by a slope factor to calculate an average risk, and multiplying by the population size is not appropriate, and risks should be summed over individuals.⁴¹

Obviously, the more relevant information one has, the less uncertain this descriptor, but in any case, the estimate used to develop the descriptor is also limited by the inherent uncertainties in risk assessment methodology, e.g., the risk estimates often being upper confidence level bounds. With the current state of the science, this descriptor should not be confused with an actuarial prediction of cases in the population (which is a statistical prediction based on a great deal of empirical data).

The second type of population risk descriptor is an estimate of the percentage of the population, or the number of persons, above a specified level of risk, RfD, RfC, LOAEL, or other specific level of interest. This descriptor must be obtained by measuring or simulating the population distribution, which can be done in several ways.

First, if the population being studied is small enough, it may be possible to measure the distribution of exposure or dose. Usually, this approach can be moderately to highly costly, but it may be the most accurate. Possible problems with this approach are lack of measuring techniques for the chemical of interest, the availability of a suitable population subset to monitor, and the problem of extrapolating short-term measurements to long-term exposures.

Second, the distribution itself may be simulated from a model such as an exposure model (a model that reports exposures or doses by linking concentrations with contact times for subsets of the population, such as those living various distances from a source) or a Monte Carlo simulation. Although this may be considerably less costly than measurements, it will probably be less accurate, especially near the high end of the distribution. Although models and statistical simulations can be fairly

accurate if the proper input data are available, these data are often difficult to obtain and assumptions must be made; use of assumptions may reduce the certainty of the estimated results.

Third, it may be possible to estimate how many people are above a certain exposure, dose, or risk level by identifying and enumerating certain population segments known to be at higher exposure, dose, sensitivity, or risk than the level of interest.

For those who use the assessments, this descriptor can be used in the evaluation of options if a level can be identified as an exposure, dose, or risk level of concern. The options can then be evaluated by estimating how many persons would go from the higher category to the lower category after the option is implemented.

Questions about the distribution of exposure, dose, and risk often require the use of additional risk descriptors. In considering the risks posed by the particular situation being evaluated, a risk manager might want to know how various subgroups fall within the distribution, and if there are any particular subgroups at disproportionately high risk.

It is often helpful for the risk assessor to describe risk by an identification, and if possible, characterization and quantification of the magnitude of the risk for specific highly exposed subgroups within the population. This descriptor is useful when there is (or is expected to be) a subgroup experiencing significantly different exposures or doses from that of the larger population.

It is also helpful to describe risk by an identification, and if possible, characterization and quantification of the magnitude of risk for specific highly sensitive or highly susceptible subgroups within the population. This descriptor is useful when the sensitivity or susceptibility to the effect for specific subgroups within the population is (or is expected to be) significantly different from that of the larger population. In order to calculate risk for these subgroups, it will sometimes be necessary to use a different dose-response relationship.

Generally, selection of the subgroups or population segments is a matter of either *a priori* interest in the subgroup, in which case the risk manager and risk assessor can jointly agree on which subgroups to highlight, or a matter of discovery of a subgroup during the assessment process. In either case, the subgroup can be treated as a population in itself and characterized the same way as the larger population using the descriptors for population and individual risk.

Exposures and doses for highly-exposed subpopulations can be calculated by defining the population segment as a population, then estimating the doses as for a population. The assessor must make it clear exactly which population was considered.

A special case of a subpopulation is that of children. For exposures that take place during childhood, when low body weight results in a higher dose rate than would be calculated using the LADD_{pot} (Equation 2-6), it is appropriate to average the dose rate (intake rate/body weight) rather than dose. The LADD_{pot} equation then becomes

$$LADD_{pot} = \sum_i \{ \bar{C}_i \cdot (\bar{IR} / BW)_i \cdot (ED_i / LT) \} \quad (5-1)$$

where LADD_{pot} is the lifetime average daily potential dose, ED_i is the exposure duration (time over which the contact actually takes place), \bar{C}_i is the average exposure concentration during period of calendar time ED_i, IR_i is the average ingestion or inhalation rate during ED_i, BW_i is body weight during exposure duration ED_i, and LT is the averaging time, in this case, a lifetime (converted to days). This form of the LADD_{pot} equation, if applied to an exposure that occurs primarily in childhood (for example, inadvertent soil ingestion), may result in an LADD_{pot} calculation somewhat higher than that obtained by using Equation 2-6, but there is some evidence that it is more defensible (Kodell *et al.*, 1987; additional discussion in memorandum from Hugh McKinnon, EPA, to Michael Callahan, EPA, November 9, 1990).

6. Assessing Uncertainty

Assessing uncertainty may involve simple or very sophisticated techniques, depending on the requirements of the assessment. Uncertainty characterization and uncertainty assessment are two activities that lead to different degrees of sophistication in describing uncertainty. Uncertainty characterization generally involves a qualitative discussion of the thought processes that lead to the selection and rejection of specific data, estimates, scenarios, etc. For simple exposure assessments, where not much quantitative information is available, uncertainty characterization may be all that is necessary.

The uncertainty assessment is more quantitative. The process begins with simpler measures (i.e., ranges) and simpler analytical techniques (i.e., sensitivity analysis), and progresses, to the extent needed to support the decision for which the exposure

⁴¹ In these cases, a significant problem can be the lack of a constant (or nearly constant) "slope factor" that would be appropriate over a wide exposure/dose range, since the dose-response curve may have thresholds, windows, or other discontinuities.

assessment is conducted, to more complex measures and techniques. The development and implementation of an appropriate uncertainty assessment strategy can be viewed as a decision process. Decisions are made about ways to characterize and analyze uncertainties, and whether to proceed to increasingly more complex levels of uncertainty assessment.

6.1. Role of Uncertainty Analysis in Exposure Assessment

Exposure assessment uses a wide array of information sources and techniques. Even where actual exposure-related measurements exist, assumptions or inferences will still be required (see section 5.2). Most likely, data will not be available for all aspects of the exposure assessment and those data that are available may be of questionable or unknown quality. In these situations, the exposure assessor will have to rely on a combination of professional judgment, inferences based on analogy with similar chemicals and conditions, estimation techniques, and the like. The net result is that the exposure assessment will be based on a number of assumptions with varying degrees of uncertainty.

The decision analysis literature has focused on the importance of explicitly incorporating and quantifying scientific uncertainty in risk assessments (Morgan, 1983; Finkel, 1990). Reasons for addressing uncertainties in exposure assessments include:

- Uncertain information from different sources of different quality must be combined.
- A decision must be made about whether and how to expend resources to acquire additional information (e.g., production, use, and emissions data; environmental fate information; monitoring data; population data) to reduce the uncertainty.
- There is considerable empirical evidence that biases may result in so-called best estimates that are not actually very accurate. Even if all that is needed is a best-estimate answer, the quality of that answer may be improved by an analysis that incorporates a frank discussion of uncertainty.
- Exposure assessment is an iterative process. The search for an adequate and robust methodology to handle the problem at hand may proceed more effectively, and to a more certain conclusion, if the associated uncertainty is explicitly included and can be used as a guide in the process of refinement.
- A decision is rarely made on the basis of a single piece of analysis. Further, it is rare for there to be one discrete decision; a process of multiple

decisions spread over time is the more common occurrence. Chemicals of concern may go through several levels of risk assessment before a final decision is made. Within this process, decisions may be made based on exposure considerations. An exposure analysis that attempts to characterize the associated uncertainty allows the user or decision-maker to better evaluate it in the context of the other factors being considered.

- Exposure assessors have a responsibility to present not just numbers but also a clear and explicit explanation of the implications and limitations of their analyses. Uncertainty characterization helps carry out this responsibility.

Essentially, the construction of scientifically sound exposure assessments and the analysis of uncertainty go hand in hand. The reward for analyzing uncertainties is knowing that the results have integrity or that significant gaps exist in available information that can make decision-making a tenuous process.

6.2. Types of Uncertainty

Uncertainty in exposure assessment can be classified into three broad categories:

1. Uncertainty regarding missing or incomplete information needed to fully define the exposure and dose (scenario uncertainty).
2. Uncertainty regarding some parameter (parameter uncertainty).
3. Uncertainty regarding gaps in scientific theory required to make predictions on the basis of causal inferences (model uncertainty).

Identification of the sources of uncertainty in an exposure assessment is the first step toward eventually determining the type of action necessary to reduce that uncertainty. The three types of uncertainty mentioned above can be further defined by examining some principal causes for each.

Exposure assessments often are developed in a phased approach. The initial phase usually involves some type of broad-based screening in which the scenarios that are not expected to pose a risk to the receptor are eliminated from a more detailed, resource-intensive review, usually through developing bounding estimates. These screening-level scenarios often are constructed to represent exposures that would fall beyond the extreme upper end of the expected exposure distribution. Because the screening-level assessments for these nonproblem scenarios usually are included in the final exposure assessment document, this final document may contain scenarios that

differ quite markedly in level of sophistication, quality of data, and amenability to quantitative expressions of uncertainty. These also can apply to the input parameters used to construct detailed exposure scenarios.

The following sections will discuss sources, characterization, and methods for analyzing the different types of uncertainty.

6.2.1. Scenario Uncertainty

The sources of scenario uncertainty include descriptive errors, aggregation errors, errors in professional judgment, and incomplete analysis.

Descriptive errors include errors in information, such as the current producers of the chemical and its industrial, commercial, and consumer uses. Information of this type is the foundation for the eventual development of exposure pathways, scenarios, exposed populations, and exposure estimates.

Aggregation errors arise as a result of lumping approximations. Included among these are assumptions of homogeneous populations, and spatial and temporal approximations such as assumptions of steady-state conditions.

Professional judgment comes into play in virtually every aspect of the exposure assessment process, from defining the appropriate exposure scenarios, to selecting the proper environmental fate models, to determining representative environmental conditions, etc. Errors in professional judgment also are a source of uncertainty.

A potentially serious source of uncertainty in exposure assessments arises from incomplete analysis. For example, the exposure assessor may overlook an important consumer exposure due to lack of information regarding the use of a chemical in a particular product. Although this source of uncertainty is essentially unquantifiable, it should not be overlooked by the assessor. At a minimum, the rationale for excluding particular exposure scenarios should be described and the uncertainty in those decisions should be characterized as high, medium, or low. The exposure assessor should discuss whether these decisions were based on actual data, analogues, or professional judgment. For situations in which the uncertainty is high, one should perform a reality check where credible upper limits on the exposure are established by a "what if" analysis.

Characterization of the uncertainty associated with nonnumeric assumptions (often relating to setting the assessment's direction and scope) will

generally involve a qualitative discussion of the rationale used in selecting specific scenarios. The discussion should allow the reader to make an independent judgment about the validity of the conclusions reached by the assessor by describing the uncertainty associated with any inferences, extrapolations, and analogies used and the weight of evidence that led the assessor to particular conclusions.

6.2.2. Parameter Uncertainty

Sources of parameter uncertainty include measurement errors, sampling errors, variability, and use of generic or surrogate data.

Measurement errors can be random or systematic. Random error results from imprecision in the measurement process. Systematic error is a bias or tendency away from the true value.

Sampling errors concern sample representativeness. The purpose of sampling is to make an inference about the nature of the whole from a measurement of a subset of the total population. If the exposure assessment uses data that were generated for another purpose, for example, consumer product preference surveys or compliance monitoring surveys, uncertainty will arise if the data do not represent the exposure scenario being analyzed.

The inability to characterize the inherent variability in environmental and exposure-related parameters is a major source of uncertainty. For example, meteorological and hydrological conditions may vary seasonally at a given location, soil conditions can have large spatial variability, and human activity patterns can vary substantially depending on age, sex, and geographical location.

The use of generic or surrogate data is common when site-specific data are not available. Examples include standard emission factors for industrial processes, generalized descriptions of environmental settings, and data pertaining to structurally related chemicals as surrogates for the chemical of interest. This is an additional source of uncertainty, and should be avoided if actual data can be obtained.

The approach to characterizing uncertainty in parameter values will vary. It can involve an order-of-magnitude bounding of the parameter range when uncertainty is high, or a description of the range for each of the parameters including the lower- and upper-bound and the best estimate values and justification for these based on available data or professional judgment. In some circumstances,

characterization can take the form of a probabilistic description of the parameter range. The appropriate characterization will depend on several factors, including whether a sensitivity analysis indicates that the results are significantly affected by variations within the range. When the results are significantly affected by a particular parameter, the exposure assessor should attempt to reduce the uncertainty by developing a description of the likely occurrence of particular values within the range. If enough data are available, standard statistical methods can be used to obtain a meaningful representation. If available data are inadequate, then expert judgments can be used to develop a subjective probabilistic representation. Expert judgments should be developed in a consistent, well-documented manner. Examples of techniques to solicit expert judgments have been described (Morgan *et al.*, 1979; Morgan *et al.*, 1984; Rish, 1988).

Most approaches for analyzing uncertainty have focused on techniques that examine how uncertainty in parameter values translates into overall uncertainty in the assessment. Several published reports (Cox and Baybutt, 1981; U.S. EPA, 1985f; Inman and Helton, 1988; Seller, 1987; Rish and Marnicio, 1988) have reviewed the many techniques available; the assessor should consult these for details. In general, these approaches can be described, in order of increasing complexity and data requirements, as either sensitivity analysis, analytical uncertainty propagation, probabilistic uncertainty analysis, or classical statistical methods.

Sensitivity analysis is the process of changing one variable while leaving the others constant and determining the effect on the output. The procedure involves fixing each uncertain quantity, one at a time, at its credible lower-bound and then its upper-bound (holding all others at their medians), and then computing the outcomes for each combination of values. These results are useful to identify the variables that have the greatest effect on exposure and to help focus further information gathering. The results do not provide any information about the probability of a quantity's value being at any level within the range; therefore, this approach is most useful at the screening level when deciding about the need and direction of further analyses.

Analytical uncertainty propagation involves examining how uncertainty in individual parameters affects the overall uncertainty of the exposure assessment. Intuitively, it seems clear that

uncertainty in a specific parameter may propagate very differently through a model than another variable having approximately the same uncertainty. Some parameters are more important than others, and the model structure is designed to account for the relative sensitivity. Thus, uncertainty propagation is a function of both the data and the model structure. Accordingly, both model sensitivity and input variances are evaluated in this procedure. Application of this approach to exposure assessment requires explicit mathematical expressions of exposure, estimates of the variances for each of the variables of interest, and the ability either analytically or numerically to obtain a mathematical derivative of the exposure equation.

Although uncertainty propagation is a powerful tool, it should be applied with caution, and the assessor should consider several points. It is difficult to generate and solve the equations for the sensitivity coefficients. In addition, the technique is most accurate for linear equations, so any departure from linearity must be carefully evaluated. Assumptions, such as independence of variables and normality of errors in the variables, need to be checked. Finally, this approach requires estimates of parameter variance, and the information to support these may not be readily available.

Probabilistic uncertainty analysis is generally considered the next level of refinement. The most common example is the Monte Carlo technique where probability density functions are assigned to each parameter, then values from these distributions are randomly selected and inserted into the exposure equation. After this process is completed many times, a distribution of predicted values results that reflects the overall uncertainty in the inputs to the calculation.

The principal advantage of the Monte Carlo method is its very general applicability. There is no restriction on the form of the input distributions or the nature of the relationship between input and output; computations are also straightforward. There are some disadvantages as well as inconveniences, however. The exposure assessor should only consider using this technique when there are credible distribution data (or ranges) for most key variables. Even if these distributions are known, it may not be necessary to apply this technique. For example, if only average exposure values are needed, these can often be computed as accurately by using average values for each of the input parameters. Another

inconvenience is that the sensitivity of the results to the input distributions is somewhat cumbersome to assess. Changing the distribution of only one value requires rerunning the entire calculation (typically, several hundreds or thousands of times). Finally, Monte Carlo results do not tell the assessor which variables are the most important contributors to output uncertainty. This is a disadvantage since most analyses of uncertainty are performed to find effective ways to reduce uncertainty.

Classical statistical methods can be used to analyze uncertainty in measured exposures. Given a data set of measured exposure values for a series of individuals, the population distribution may be estimated directly, provided that the sample design was developed properly to capture a representative sample. The measured exposure values also may be used to directly compute confidence interval estimates for percentiles of the exposure distribution (American Chemical Society, 1988). When the exposure distribution is estimated from measured exposures for a probability sample of population members, confidence interval estimates for percentiles of the exposure distribution are the primary uncertainty characterization. Data collection survey design should also be discussed, as well as accuracy and precision of the measurement techniques.

Often the observed exposure distribution is skewed; many sample members have exposure distributions at or below the detection limit. In this situation, estimates of the exposure distribution may require a very large sample size. Fitting the data to a distribution type can be problematic in this situation because data are usually scant in the low probability areas (the tails) where numerical values vary widely. As a consequence, for data sets for which the sampling has been completed, means and standard deviations may be determined to a good approximation, but characterization of the tails of the distribution will have much greater uncertainty. This difference should be brought out in the discussion. For data sets for which sampling is still practical, stratification of the statistical population to oversample the tail may give more precision and confidence in the information in the tail area of the distribution.

6.2.3. Model Uncertainty

At a minimum, the exposure assessor should describe in qualitative terms the rationale for selection of any conceptual and mathematical models. This discussion should address the status of

these approaches and any plausible alternatives in terms of their acceptance by the scientific community, how well the model(s) represents the situation being assessed, e.g., high end estimate, and to what extent verification and validation have been done. Relationship errors and modeling errors are the primary sources of modeling uncertainty.

Relationship errors include errors in correlations between chemical properties, structure-reactivity correlations, and environmental fate models. In choosing to use these tools, the exposure assessor must decide among the many possible functional forms available. Even though statistics on the performance of the methodology for a given test set of chemicals may be available and can help guide in the selection process, the exposure assessor must decide on the most appropriate methodology for the chemical of interest based on the goals of the assessment.

Modeling errors are due to models being simplified representations of reality, for example approximating a three-dimensional aquifer with a two-dimensional mathematical model. Even after the exposure assessor has selected the most appropriate model for the purpose at hand, one is still faced with the question of how well the model represents the real situation. This question is compounded by the overlap between modeling uncertainties and other uncertainties, e.g., natural variability in environmental inputs, representativeness of the modeling scenario, and aggregation errors. The dilemma facing exposure assessors is that many existing models (particularly the very complex ones) and the hypotheses contained within them cannot be fully tested (Beck, 1987), although certain components of the model may be tested. Even when a model has been validated under a particular set of conditions, uncertainty will exist in its application to situations beyond the test system.

A variety of approaches can be used to quantitatively characterize the uncertainty associated with model constructs. One approach is to use different modeling formulations (including the preferred and plausible alternatives) and consider the range of the outputs to be representative of the uncertainty range. This strategy is most useful when no clear best approach can be identified due to the lack of supporting data or when the situations being assessed require extrapolation beyond the conditions for which the models were originally designed.

Where the data base is sufficient, the exposure assessor should characterize the uncertainty in the selected model by describing the validation and verification efforts. Validation is the process of examining the performance of the model compared to actual observations under situations representative of those being assessed. Approaches for model validation have been discussed (U.S. EPA 1985e). Verification is the process of confirming that the model computer code is producing the proper numerical output. In most situations, only partial validation is possible due to data deficiencies or model complexity.

6.3. Variability Within a Population Versus Uncertainty in the Estimate

For clarity, it should be emphasized that variability (the receipt of different levels of exposure by different individuals) is being distinguished from uncertainty (the lack of knowledge about the correct value for a specific exposure measure or estimate). Most of the exposure and risk descriptors discussed in this report deal with variability directly, but estimates must also be made of the uncertainty of these descriptors.⁴² This may be done qualitatively or quantitatively, and it is beyond the scope of this report to discuss the mechanics of uncertainty analysis in detail. It is an important distinction, however, since the risk assessor and risk manager need to know if the numbers being reported for exposures take variability, uncertainty, or both, into consideration.

Not all approaches historically used to construct measures or estimates of exposure attempted to distinguish variability and uncertainty. In particular, in many cases in which estimates were termed worst case, focusing on the high end of the exposed population and also selection of high-end values for uncertain physical quantities resulted in values that were seen to be quite conservative. By using both the high-end individuals (variability) and upper confidence bounds⁴³ on data or physical parameters

⁴² Each measure or estimate of exposure will have its associated uncertainty which should be addressed both qualitatively and quantitatively. For example, if population mean exposure is being addressed by use of direct personal monitoring data, qualitative issues will include the representativeness of the population monitored to the full population, the representativeness of the period selected for monitoring, and confidence that there were not systematic errors in the measured data. Quantitative uncertainty could be addressed through the use of confidence intervals for the actual mean population exposure.

⁴³ The confidence interval is interpreted as the range of values within which the assessor knows

(uncertainty), these estimates might be interpreted as "not exceeding an upper bound on exposures received by certain high-end individuals."

Note that this approach will provide an estimate that considers both variability and uncertainty, but by only reporting the upper confidence bound, it appears to be merely a more conservative estimate of the variability. High end estimates which include consideration of uncertainty should be presented with both the upper and lower uncertainty bounds on the high end estimate. This provides the necessary information to the risk manager. Without specific discussion of what was done, risk managers may view the results as not having dealt with uncertainty. It is fundamental to exposure assessment that assessors have a clear distinction between the variability of exposures received by individuals in a population, and the uncertainty of the data and physical parameters used in calculating exposure.

The discussion of estimating exposure and dose presented in Section 5.3.4 addresses the rationale and approaches for constructing a range of measures or estimates of exposure, with emphasis on how these can be used for exposure or risk characterization. The distinction between these measures or estimates (e.g., average versus high end) is often a difference in anticipated variability in the exposures received by individuals (i.e., average exposure integrates exposures across all individuals, while high-end exposure focuses on the upper percentiles of the exposed group being assessed.) Although several measures can be used to characterize risk in different ways, this does not address which of these measures or characterizations is used for decisions. The selection of the point or measure of exposure or risk upon which regulatory decisions are made is a risk management decision governed by programmatic policy, and is therefore beyond the scope of these guidelines.

7. Presenting the Results of the Exposure Assessment

One of the most important aspects of the exposure assessment is presenting the results. It is here that the assessment ultimately succeeds or fails in meeting the objectives laid out in the planning as discussed in section 3. This section discusses communication of the results, format considerations, and suggested tips for reviewing exposure assessments

either as a final check or as a review of work done by others.

7.1. Communicating the Results of the Assessment

Communicating the results of an exposure assessment is more than a simple summary of conclusions and quantitative estimates for the various pathways and routes of exposure. The most important part of an exposure assessment is the overall narrative exposure characterization, without which the assessment is merely a collection of data, calculations, and estimates. This exposure characterization should consist of discussion, analysis, and conclusions that synthesize the results from the earlier portions of the document, present a balanced representation of the available data and its relevancy to the health effects of concern, and identify key assumptions and major areas of uncertainty. Section 7.1.1 discusses the exposure characterization, and section 7.1.2 discusses how this is used in the risk characterization step of a risk assessment.

7.1.1. Exposure Characterization

The exposure characterization is the summary explanation of the exposure assessment. In this final step, the exposure characterization:

- Provides a statement of purpose, scope, level of detail, and approach used in the assessment, including key assumptions;
- Presents the estimates of exposure and dose by pathway and route for individuals, population segments, and populations in a manner appropriate for the intended risk characterization;
- Provides an evaluation of the overall quality of the assessment and the degree of confidence the authors have in the estimates of exposure and dose and the conclusions drawn;
 - Interprets the data and results; and
 - Communicates results of the exposure assessment to the risk assessor, who can then use the exposure characterization, along with characterizations of the other risk assessment elements, to develop a risk characterization.

As part of the statement of purpose, the exposure characterization explains why the assessment was done and what questions were asked. It also reaches a conclusion as to whether the questions posed were in fact answered, and with what degree of confidence. It should also note whether the exposure assessment brought to light additional or perhaps more appropriate questions, if these were answered, and if so, with what degree of confidence.

The statement of scope discusses the geographical or demographic boundaries of the assessment. The specific populations and population segments that were the subjects of the assessment are clearly identified, and the reasons for their selection and any exclusions are discussed. Especially sensitive groups or groups that may experience unusual exposure patterns are highlighted.

The characterization also discusses whether the scope and level of detail of the assessment were ideal for answering the questions of the assessment and whether limitations in scope and level of detail were made because of technical, practical, or financial reasons, and the implications of these limitations on the quality of the conclusions.

The methods used to quantify exposure and dose are clearly stated in the exposure characterization. If models are used, the basis for their selection and validation status is described. If measurement data are used, the quality of the data is discussed. The strengths and weaknesses of the particular methods used to quantify exposure and dose are described, along with comparison and contrast to alternate methods, if appropriate.

In presenting the exposure and dose estimates, the important sources, pathways, and routes of exposure are identified and quantified, and reasons for excluding any from the assessment are discussed.

A variety of risk descriptors, and where possible, the full population distribution is presented. Risk managers should be given some sense of how exposure is distributed over the population and how variability in population activities influences this distribution. Ideally, the exposure characterization links the purpose of the assessment with specific risk descriptors, which in turn are presented in such a way as to facilitate construction of a risk characterization.

A discussion of the quality of the exposure and dose estimates is critical to the credibility of the assessment. This may be based in part on a quantitative uncertainty analysis, but the exposure characterization must explain the results of any such analysis in terms of the degree of confidence to be placed in the estimates and conclusions drawn.

Finally, a description of additional research and data needed to improve the exposure assessment is often helpful to risk managers in making decisions about improving the quality of the assessment. For this reason, the exposure characterization should identify key data gaps that can help

the true measure lies, with specified statistical confidence. The upper bound confidence limit is the higher of the two ends of the confidence interval.

focus further efforts to reduce uncertainty.

Additional guidance on communicating the results of an exposure assessment can be found in the proceedings of a recent workshop on risk communication (American Industrial Health Council, 1989).

7.1.2. Risk Characterization

Most exposure assessments will be done as part of a risk assessment, and the exposure characterization must be useful to the risk assessor in constructing a risk characterization. Risk characterization is the integration of information from hazard identification, dose-response assessment, and exposure assessment into a coherent picture. A risk characterization is a necessary part of any Agency report on risk whether the report is a preliminary one prepared to support allocation of resources toward further study or a comprehensive one prepared to support regulatory decisions.

Risk characterization is the culmination of the risk assessment process. In this final step, the risk characterization:

- Integrates the individual characterizations from the hazard identification, dose-response, and exposure assessments;
- Provides an evaluation of the overall quality of the assessment and the degree of confidence the authors have in the estimates of risk and conclusions drawn;
- Describes risks to individuals and populations in terms of extent and severity of probable harm; and
- Communicates results of the risk assessment to the risk manager.

It provides a scientific interpretation of the assessment. The risk manager can then use the risk assessment, along with other risk management elements, to make public health decisions. The following sections describe these four aspects of the risk characterization in more detail.

7.1.2.1. Integration of Hazard Identification, Dose-Response, and Exposure Assessments

In developing the hazard identification, dose-response, and exposure portions of the risk assessment, the assessor makes many judgments concerning the relevance and appropriateness of data and methodology. These judgments are summarized in the individual characterizations for hazard identification, dose-response, and exposure. In integrating the parts of the assessment, the risk assessor

determines if some of these judgments have implications for other parts of the assessment, and whether the parts of the assessment are compatible. For example, if the hazard identification assessment determines that a chemical is a developmental toxicant but not a carcinogen, the dose-response and exposure information is presented accordingly; this differs greatly from the way the presentation is made if the chemical is a carcinogen but not a developmental toxicant.

The risk characterization not only examines these judgments, but also explains the constraints of available data and the state of knowledge about the phenomena studied in making them, including:

- The qualitative, weight-of-evidence conclusions about the likelihood that the chemical may pose a specific hazard (or hazards) to human health, the nature and severity of the observed effects, and by what route(s) these effects are seen to occur. These judgments affect both the dose-response and exposure assessments;
- For noncancer effects, a discussion of the dose-response behavior of the critical effect(s), data such as the shapes and slopes of the dose-response curves for the various other toxic endpoints, and how this information was used to determine the appropriate dose-response assessment technique; and
- The estimates of the magnitude of the exposure, the route, duration and pattern of the exposure, relevant pharmacokinetics, and the number and characteristics of the population exposed. This information must be compatible with both the hazard identification and dose-response assessments.

The presentation of the integrated results of the assessment draws from and highlights key points of the individual characterizations of hazard, dose-response, and exposure analysis performed separately under these Guidelines. The summary integrates these component characterizations into an overall risk characterization.

7.1.2.2. Quality of the Assessment and Degree of Confidence

The risk characterization summarizes the data brought together in the analysis and the reasoning upon which the assessment is based. The description also conveys the major strengths and weaknesses of the assessment that arise from data availability and the current limits of understanding of toxicity mechanisms.

Confidence in the results of a risk assessment is consequently a function of confidence in the results of analysis of

each element: hazard, dose-response, and exposure. Each of these three elements has its own characterization associated with it. For example, the exposure assessment component includes an exposure characterization. Within each characterization, the important uncertainties of the analysis and interpretation of data are explained so that the risk manager is given a clear picture of any consensus or lack thereof about significant aspects of the assessment. For example, whenever more than one view of dose-response assessment is supported by the data and by the policies of these Guidelines, and choosing between them is difficult, the views are presented together. If one has been selected over another, the rationale is given; if not, then both are presented as plausible alternatives.

If a quantitative uncertainty analysis is appropriate, it is summarized in the risk characterization; in any case a qualitative discussion of important uncertainties is appropriate. If other organizations, such as other Federal agencies, have published risk assessments, or prior EPA assessments have been done on the substance or an analogous substance and have relevant similarities or differences, these too are described.

7.1.2.3. Descriptors of Risk

There are a number of different ways to describe risk in quantitative or qualitative terms. Section 2.3 explains how risk descriptors are used. It is important to explain what aspect of the risk is being described, and how the exposure data and estimates are used to develop the particular descriptor.

7.1.2.4. Communicating Results of a Risk Assessment to the Risk Manager

Once the risk characterization is completed, the focus turns to communicating results to the risk manager. The risk manager uses the results of the risk characterization, technologic factors, and socioeconomic considerations in reaching a regulatory decision. Because of the way these risk management factors may impact different cases, consistent, but not necessarily identical, risk management decisions must be made on a case-by-case basis. Consequently, it is entirely possible and appropriate that a chemical with a specific risk characterization may be regulated differently under different statutes. These Guidelines are not intended to give guidance on the nonscientific aspects of risk management decisions.

7.1.3. Establishing the Communication Strategy

For assessments that must be explained to the general public, a communication strategy is often required. Although risk communication is often considered a part of risk management, it involves input from the exposure and risk assessors; early planning for a communication strategy can be very helpful to the ultimate risk communication.

The EPA has guidance on preparing communication strategies (U.S. EPA, 1988g). Additional sources of information are the New Jersey Department of Environmental Protection (1988a, 1988b) and the NRC (1989b). These documents, and the sources listed within them, are valuable resources for all who will be involved with the sensitive issues of explaining environmental health risks. The NRC (1989b, p. 148) states:

"It is a mistake to simply consider risk communication to be an add-on activity for either scientific or public affairs staffs; both elements should be involved. There are clear dangers if risk messages are formulated ad hoc by public relations personnel in isolation from available technical expertise; neither can they be prepared by risk analysts as a casual extension of their analytic duties."

7.2. Format for Exposure Assessment Reports

The Agency does not require a set format for exposure assessment reports, but individual program offices within the Agency may have specific format requirements. Section 3 illustrates that exposure assessments are performed for a variety of purposes, scopes, and levels of detail, and use a variety of approaches. While it is impractical for the Agency to specify an outline format for all types of assessments being performed within the Agency, program offices are encouraged to use consistent formats for similar types of assessments within their own purview.

All exposure assessments must, at a minimum, contain a narrative exposure characterization section that contains the types of information discussed in section 7.1. For the purpose of consistency, this section should be titled exposure characterization. Placement of this section within the assessment is optional, but it is strongly suggested that it be prominently featured in the assessment. It is not, however, an executive summary and should not be used interchangeably with one.

7.3. Reviewing Exposure Assessments

This section provides some suggestions on how to effectively review an exposure assessment and highlights some of the common pitfalls. The emphasis in these Guidelines has been on how to properly conduct exposure assessments; this section can serve as a final checklist in reviewing the completed assessment. An exposure assessor also may be called upon to critically review and evaluate exposure assessments conducted by others; these suggestions should be helpful in this regard.

Reviewers of exposure assessments are usually asked to identify inconsistencies with the underlying science and with Agency-developed guidelines, factors, and methodologies, and to determine the effect these inconsistencies might have on the results and conclusions of the exposure assessment. Often the reviewer can only describe whether these inconsistencies or deficiencies might underestimate or overestimate exposure.

Some of the questions a reviewer should ask to identify the more common pitfalls that tend to underestimate exposure are:

Has the pathways analysis been broad enough to avoid overlooking a significant pathway?

For example, in evaluating exposure to soil contaminated with PCBs, the exposure assessment should not be limited only to evaluating the dermal contact pathway. Other pathways, such as inhalation of dust and vapors or the ingestion of contaminated gamefish from an adjacent stream receiving surface runoff containing contaminated soil, should also be evaluated as they could contribute higher levels of exposure from the same source.

Have all the contaminants of concern in a mixture been evaluated?

Since risks resulting from exposures to complex mixtures of chemicals with the same mode of toxic action are generally treated as additive (by summing the risks) in a risk assessment, failure to evaluate one or more of the constituents would neglect its contribution to the total exposure and risk. This is especially critical for relatively toxic or potent chemicals that tend to drive risk estimates even when present in relatively low quantities.

Have exposure levels or concentration measurements been compared with appropriate background levels?

Contaminant concentrations or exposure levels should not be compared with other contaminated media or exposed populations. When comparing

with background levels, the exposure assessor must determine whether these concentrations or exposure levels are also affected by contamination from anthropogenic activities.

Were the detection limits sensitive enough to make interpretations about exposures at levels corresponding to health concerns? Were the data interpreted correctly?

Because values reported as not detected (ND) mean only that the chemical of interest was not found at the particular detection limit used in the laboratory analysis, ND does not rule out the possibility that the chemical may be present in significant concentrations. Depending on the purpose and the degree of conservatism warranted in the exposure assessment, results reported as ND should be handled as discussed in Section 5.

Has the possibility of additive pathways been considered for the population being studied?

If the purpose of the exposure assessment is to evaluate the total exposure and risk of a population, then exposures from individual pathways within the same route may be summed in cases which concurrent exposures can realistically be expected to occur.

Some questions a reviewer should ask to avoid the more prevalent errors that generally tend to overestimate exposure are:

Have unrealistically conservative exposure parameters been used in the scenarios?

The exposure assessor must conduct a reality check to ensure that the exposure cases used in the scenario(s) (except bounding estimates) could actually occur.

Have potential exposures been presented as existing exposures?

In many situations, especially when the scenario evaluation approach is used, the objective of the assessment is to estimate potential exposures. (That is, if a person were to be exposed to these chemicals under these conditions, then the resultant exposure would be this much.) In determining the need and urgency for regulatory action, risk managers often weigh actual exposures more heavily than higher levels of potential exposures. Therefore, the exposure assessment should clearly note whether the results represent actual or potential exposures.

Have exposures derived from "not detected" levels been presented as actual exposures?

For some exposure assessments it may be appropriate to assume that a chemical reported as not detected is present at either the detection limit or

one-half the detection limit. The exposure estimates derived from these nondetects, however, should be clearly labeled as hypothetical since they are based on the conservative assumption that chemicals are present at or below the detection limit, when, in fact, they may not be present at all. Exposures, doses, or risks estimated from data using substituting values of detection limits for "not detected" samples must be reported as "less than" the resulting exposure, dose, or risk estimate.

Questions a reviewer should ask to identify common errors that may underestimate or overestimate exposure are:

Are the results presented with an appropriate number of significant figures?

The number of significant figures should reflect the uncertainty of the numeric estimate. If the likely range of the results spans several orders of magnitude, then using more than one significant figure implies more confidence in the results than is warranted.

Have the calculations been checked for computational errors?

Obviously, calculations should be checked for arithmetic errors and mistakes in converting units. This is overlooked more often than one might expect.

Are the factors for intake rates, etc. used appropriately?

Exposure factors should be checked to ensure that they correspond to the site or situation being evaluated.

Have the uncertainties been adequately addressed?

Exposure assessment is an inexact science, and the confidence in the results may vary tremendously. It is essential the exposure assessment include an uncertainty assessment that places these uncertainties in perspective.

If Monte Carlo simulations were used, were correlations among input distributions known and properly accounted for? Is the maximum value simulated by this method in fact a bounding estimate? Was Monte Carlo simulation necessary?

(A Monte Carlo simulation randomly selects the values from the input parameters to simulate an individual. If data already exist to show the relationship between variables for the actual individuals, it makes little sense to use Monte Carlo simulation, since one already has the answer to the question of how the variables are related for each individual. A simulation is unnecessary.)

8. Glossary of Terms

Absorbed dose—See internal dose.

Absorption barrier—Any of the exchange barriers of the body that allow differential diffusion of various substances across a boundary. Examples of absorption barriers are the skin, lung tissue, and gastrointestinal tract wall.

Accuracy—The measure of the correctness of data, as given by the difference between the measured value and the true or standard value.

Administered dose—The amount of a substance given to a test subject (human or animal) in determining dose-response relationships, especially through ingestion or inhalation. In exposure assessment, since exposure to chemicals is usually inadvertent, this quantity is called potential dose.

Agent—A chemical, physical, mineralogical, or biological entity that may cause deleterious effects in an organism after the organism is exposed to it.

Ambient—The conditions surrounding a person, sampling location, etc.

Ambient measurement—A measurement (usually of the concentration of a chemical or pollutant) taken in an ambient medium, normally with the intent of relating the measured value to the exposure of an organism that contacts that medium.

Ambient medium—One of the basic categories of material surrounding or contacting an organism, e.g., outdoor air, indoor air, water, or soil, through which chemicals or pollutants can move and reach the organism. (See also biological medium, environmental medium)

Applied dose—The amount of a substance in contact with the primary absorption boundaries of an organism (e.g., skin, lung, gastrointestinal tract) and available for absorption.

Arithmetic mean—The sum of all the measurements in a data set divided by the number of measurements in the data set.

Background level (environmental)—The concentration of substance in a defined control area during a fixed period of time before, during, or after a data-gathering operation.

Breathing zone—A zone of air in the vicinity of an organism from which respired air is drawn. Personal monitors are often used to measure pollutants in the breathing zone.

Bias—A systematic error inherent in a method or caused by some feature of the measurement system.

Bioavailability—The state of being capable of being absorbed and available to interact with the metabolic processes of an organism. Bioavailability is typically a function of chemical properties, physical state of the material to which an organism is exposed, and

the ability of the individual organism to physiologically take up the chemical.

Biological marker of exposure (sometimes referred to as a biomarker of exposure)—Exogenous chemicals, their metabolites, or products of interactions between a xenobiotic chemical and some target molecule or cell that is measured in a compartment within an organism.

Biological measurement—A measurement taken in a biological medium. For the purpose of exposure assessment via reconstruction of dose, the measurement is usually of the concentration of a chemical/metabolite or the status of a biomarker, normally with the intent of relating the measured value to the internal dose of a chemical at some time in the past. (Biological measurements are also taken for purposes of monitoring health status and predicting effects of exposure.) (See also ambient measurement)

Biological medium—One of the major categories of material within an organism, e.g., blood, adipose tissue, or breath, through which chemicals can move, be stored, or be biologically, physically, or chemically transformed. (See also ambient medium, environmental medium)

Biologically effective dose—The amount of a deposited or absorbed chemical that reaches the cells or target site where an adverse effect occurs, or where that chemical interacts with a membrane surface.

Blank (blank sample)—An unexposed sampling medium, or an aliquot of the reagents used in an analytical procedure, in the absence of added analyte. The measured value of a blank sample is the blank value.

Body burden—The amount of a particular chemical stored in the body at a particular time, especially a potentially toxic chemical in the body as a result of exposure. Body burdens can be the result of long-term or short-term storage, for example, the amount of a metal in bone, the amount of a lipophilic substance such as PCB in adipose tissue, or the amount of carbon monoxide (as carboxyhemoglobin) in the blood.

Bounding estimate—An estimate of exposure, dose, or risk that is higher than that incurred by the person in the population with the highest exposure, dose, or risk. Bounding estimates are useful in developing statements that exposures, doses, or risks are "not greater than" the estimated value.

Comparability—The ability to describe likenesses and differences in the quality and relevance of two or more data sets.

Data quality objectives (DQO)—Qualitative and quantitative statements of the overall level of uncertainty that a decision-maker is willing to accept in results or decisions derived from environmental data. DQOs provide the statistical framework for planning and managing environmental data operations consistent with the data user's needs.

Dose—The amount of a substance available for interaction with metabolic processes or biologically significant receptors after crossing the outer boundary of an organism. The potential dose is the amount ingested, inhaled, or applied to the skin. The applied dose is the amount of a substance presented to an absorption barrier and available for absorption (although not necessarily having yet crossed the outer boundary of the organism). The absorbed dose is the amount crossing a specific absorption barrier (e.g., the exchange boundaries of skin, lung, and digestive tract) through uptake processes. Internal dose is a more general term denoting the amount absorbed without respect to specific absorption barriers or exchange boundaries. The amount of the chemical available for interaction by any particular organ or cell is termed the delivered dose for that organ or cell.

Dose rate—Dose per unit time, for example in mg/day, sometimes also called dosage. Dose rates are often expressed on a per-unit-body-weight basis, yielding units such as mg/kg/day (mg/kg-day). They are also often expressed as averages over some time period, for example a lifetime.

Dose-response assessment—The determination of the relationship between the magnitude of administered, applied, or internal dose and a specific biological response. Response can be expressed as measured or observed incidence, percent response in groups of subjects (or populations), or the probability of occurrence of a response in a population.

Dose-response curve—A graphical representation of the quantitative relationship between administered, applied, or internal dose of a chemical or agent, and a specific biological response to that chemical or agent.

Dose-response relationship—The resulting biological responses in an organ or organism expressed as a function of a series of different doses.

Dosimeter—Instrument to measure dose; many so-called dosimeters actually measure exposure rather than dose.

Dosimetry—Process of measuring or estimating dose.

Ecological exposure—Exposure of a nonhuman receptor or organism to a

chemical, or a radiological or biological agent.

Effluent—Waste material being discharged into the environment, either treated or untreated. Effluent generally is used to describe water discharges to the environment, although it can refer to stack emissions or other material flowing into the environment.

Environmental fate—The destiny of a chemical or biological pollutant after release into the environment.

Environmental fate involves temporal and spatial considerations of transport, transfer, storage, and transformation.

Environmental fate model—In the context of exposure assessment, any mathematical abstraction of a physical system used to predict the concentration of specific chemicals as a function of space and time subject to transport, intermedia transfer, storage, and degradation in the environment.

Environmental medium—One of the major categories of material found in the physical environment that surrounds or contacts organisms, e.g., surface water, ground water, soil, or air, and through which chemicals or pollutants can move and reach the organisms. (See ambient medium, biological medium)

Exposure—Contact of a chemical, physical, or biological agent with the outer boundary of an organism. Exposure is quantified as the concentration of the agent in the medium in contact integrated over the time duration of that contact.

Exposure assessment—The determination or estimation (qualitative or quantitative) of the magnitude, frequency, duration, and route of exposure.

Exposure concentration—The concentration of a chemical in its transport or carrier medium at the point of contact.

Exposure pathway—The physical course a chemical or pollutant takes from the source to the organism exposed.

Exposure route—The way a chemical or pollutant enters an organism after contact, e.g., by ingestion, inhalation, or dermal absorption.

Exposure scenario—A set of facts, assumptions, and inferences about how exposure takes place that aids the exposure assessor in evaluating, estimating, or quantifying exposures.

Fixed-location monitoring—Sampling of an environmental or ambient medium for pollutant concentration at one location continuously or repeatedly over some length of time.

Geometric mean—The n th root of the product of n values.

Guidelines—Principles and procedures to set basic requirements for

general limits of acceptability for assessments.

Hazard identification—A description of the potential health effects attributable to a specific chemical or physical agent. For carcinogen assessments, the hazard identification phase of a risk assessment is also used to determine whether a particular agent or chemical is, or is not, causally linked to cancer in humans.

High-end exposure (dose) estimate—A plausible estimate of individual exposure or dose for those persons at the upper end of an exposure or dose distribution, conceptually above the 90th percentile, but not higher than the individual in the population who has the highest exposure or dose.

High-end Risk Descriptor—A plausible estimate of the individual risk for those persons at the upper end of the risk distribution, conceptually above the 90th percentile but not higher than the individual in the population with the highest risk. Note that persons in the high end of the risk distribution have high risk due to high exposure, high susceptibility, or other reasons, and therefore persons in the high end of the exposure or dose distribution are not necessarily the same individuals as those in the high end of the risk distribution.

Intake—The process by which a substance crosses the outer boundary of an organism without passing an absorption barrier, e.g., through ingestion or inhalation. (See also potential dose)

Internal dose—The amount of a substance penetrating across the absorption barriers (the exchange boundaries) of an organism, via either physical or biological processes. For the purpose of these Guidelines, this term is synonymous with absorbed dose.

Limit of detection (LOD) [or Method detection limit (MDL)]—The minimum concentration of an analyte that, in a given matrix and with a specific method, has a 99% probability of being identified, qualitatively or quantitatively measured, and reported to be greater than zero.

Matrix—A specific type of medium (e.g., surface water, drinking water) in which the analyte of interest may be contained.

Maximally exposed individual (MEI)—The single individual with the highest exposure in a given population (also, most exposed individual). This term has historically been defined various ways, including as defined here and also synonymously with worst case or bounding estimate. Assessors are cautioned to look for contextual

definitions when encountering this term in the literature.

Maximum exposure range—A semiquantitative term referring to the extreme uppermost portion of the distribution of exposures. For consistency, this term (and the dose or risk analogues) should refer to the portion of the individual exposure distribution that conceptually falls above about the 98th percentile of the distribution, but is not higher than the individual with the highest exposure.

Median value—The value in a measurement data set such that half the measured values are greater and half are less.

Microenvironment method—A method used in predictive exposure assessments to estimate exposures by sequentially assessing exposure for a series of areas (microenvironments) that can be approximated by constant or well-characterized concentrations of a chemical or other agent.

Microenvironments—Well-defined surroundings such as the home, office, automobile, kitchen, store, etc. that can be treated as homogeneous (or well characterized) in the concentrations of a chemical or other agent.

Mode—The value in the data set that occurs most frequently.

Monte Carlo technique—A repeated random sampling from the distribution of values for each of the parameters in a generic (exposure or dose) equation to derive an estimate of the distribution of (exposures or doses in) the population.

Nonparametric statistical methods—Methods that do not assume a functional form with identifiable parameters for the statistical distribution of interest (distribution-free methods).

Pathway—The physical course a chemical or pollutant takes from the source to the organism exposed.

Personal measurement—A measurement collected from an individual's immediate environment using active or passive devices to collect the samples.

Pharmacokinetics—The study of the time course of absorption, distribution, metabolism, and excretion of a foreign substance (e.g., a drug or pollutant) in an organism's body.

Point-of-contact measurement of exposure—An approach to quantifying exposure by taking measurements of concentration over time at or near the point of contact between the chemical and an organism while the exposure is taking place.

Potential dose—The amount of a chemical contained in material ingested, air breathed, or bulk material applied to the skin.

Precision—A measure of the reproducibility of a measured value under a given set of conditions.

Probability samples—Samples selected from a statistical population such that each sample has a known probability of being selected.

Quality assurance (QA)—An integrated system of activities involving planning, quality control, quality assessment, reporting and quality improvement to ensure that a product or service meets defined standards of quality with a stated level of confidence.

Quality control (QC)—The overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of the users. The aim is to provide quality that is satisfactory, adequate, dependable, and economical.

Quantification limit (QL)—The concentration of analyte in a specific matrix for which the probability of producing analytical values above the method detection limit is 99%.

Random samples—Samples selected from a statistical population such that each sample has an equal probability of being selected.

Range—The difference between the largest and smallest values in a measurement data set.

Reasonable worst case—A semiquantitative term referring to the lower portion of the high end of the exposure, dose, or risk distribution. The reasonable worst case has historically been loosely defined, including synonymously with maximum exposure or worst case, and assessors are cautioned to look for contextual definitions when encountering this term in the literature. As a semiquantitative term, it is sometimes useful to refer to individual exposures, doses, or risks that, while in the high end of the distribution, are not in the extreme tail. For consistency, it should refer to a range that can conceptually be described as above the 90th percentile in the distribution, but below about the 98th percentile. (compare maximum exposure range, worst case). *

Reconstruction of dose—An approach to quantifying exposure from internal dose, which is in turn reconstructed after exposure has occurred, from evidence within an organism such as chemical levels in tissues or fluids or from evidence of other biomarkers of exposure.

Representativeness—The degree to which a sample is, or samples are, characteristic of the whole medium, exposure, or dose for which the samples are being used to make inferences.

Risk—The probability of deleterious health or environmental effects.

Risk characterization—The description of the nature and often the magnitude of human or nonhuman risk, including attendant uncertainty.

Route—The way a chemical or pollutant enters an organism after contact, e.g., by ingestion, inhalation, or dermal absorption.

Sample—A small part of something designed to show the nature or quality of the whole. Exposure-related measurements are usually samples of environmental or ambient media, exposures of a small subset of a population for a short time, or biological samples, all for the purpose of inferring the nature and quality of parameters important to evaluating exposure.

Sampling frequency—The time interval between the collection of successive samples.

Sampling plan—A set of rules or procedures specifying how a sample is to be selected and handled.

Scenario evaluation—An approach to quantifying exposure by measurement or estimation of both the amount of a substance contacted, and the frequency/duration of contact, and subsequently linking these together to estimate exposure or dose.

Source characterization measurements—Measurements made to characterize the rate of release of agents into the environment from a source of emission such as an incinerator, landfill, industrial or municipal facility, consumer product, etc.

Standard operating procedure (SOP)—A procedure adopted for repetitive use when performing a specific measurement or sampling operation.

Statistical control—The process by which the variability of measurements or of data outputs of a system is controlled to the extent necessary to produce stable and reproducible results. To say that measurements are under statistical control means that there is statistical evidence that the critical variables in the measurement process are being controlled to such an extent that the system yields data that are reproducible within well-defined limits.

Statistical significance—An inference that the probability is low that the observed difference in quantities being measured could be due to variability in the data rather than an actual difference in the quantities themselves. The inference that an observed difference is statistically significant is typically based on a test to reject one hypothesis and accept another.

Surrogate data—Substitute data or measurements on one substance used to

estimate analogous or corresponding values of another substance.

Uptake—The process by which a substance crosses an absorption barrier and is absorbed into the body.

Worst case—A semiquantitative term referring to the maximum possible exposure, dose, or risk, that can conceivably occur, whether or not this exposure, dose, or risk actually occurs or is observed in a specific population. Historically, this term has been loosely defined in an ad hoc way in the literature, so assessors are cautioned to look for contextual definitions when encountering this term. It should refer to a hypothetical situation in which everything that can plausibly happen to maximize exposure, dose, or risk does in fact happen. This worst case may occur (or even be observed) in a given population, but since it is usually a very unlikely set of circumstances, in most cases, a worst-case estimate will be somewhat higher than occurs in a specific population. As in other fields, the worst-case scenario is a useful device when low probability events may result in a catastrophe that must be avoided even at great cost, but in most health risk assessments, a worst-case scenario is essentially a type of bounding estimate.

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- Part B: Response to Public and Science Advisory Board Comments**
- 1. Introduction**
- This section summarizes the major issues raised in public comments on the Proposed Guidelines for Exposure-Related Measurements (hereafter "1988 Proposed Guidelines") published December 2, 1988 (53 FR 48830-48853). In addition to general comments, reviewers were requested to comment specifically on the guidance for interpreting contaminated blanks versus field data, the interpretation of data at or near the limit of detection, approaches to assessing uncertainty, and the Glossary of Terms. Comment was also invited on the following questions: Should the 1988 Proposed Guidelines be combined with the 1986 Guidelines for Estimating Exposures (hereafter "1986 Guidelines")? Is the current state-of-the-art in making measurements of population activities for the purpose of exposure assessment advanced to the point where the Agency can construct guidelines in this area? Given that EPA Guidelines are not protocols or detailed literature reviews, is the level of detail useful and appropriate, especially in the area of statistics?
- The Science Advisory Board (SAB) met on December 2, 1988, and provided written comments in a May, 1989 letter to the EPA Administrator (EPA-SAB-EETFC-89-020). The public comment period extended until March 2, 1989. Comments were received from 17 individuals or organizations.
- After the SAB and public comment, Agency staff prepared summaries of the comments and analyses of major issues presented by the commentors. These were considered in the development of these final Guidelines. In response to the comments, the Agency has modified or clarified most of the sections of the Guidelines. For the purposes of this discussion, only the most significant issues reflected by the public and SAB comments are discussed. Several minor recommendations, which do not warrant discussion here, were considered and adopted by the Agency in the revision of these Guidelines.
- The EPA revised the 1988 Proposed Guidelines in accordance with the public and SAB comments, retitling them Guidelines for Exposure Assessment (hereafter "Guidelines"). The Agency presented the draft final Guidelines to the SAB at a public meeting on September 12, 1991, at which time the SAB invited public comment for a period of 30 days on the draft. The SAB discussed the final draft in a January 13, 1992 letter to the Administrator of the EPA (EPA-SAB-IAQC-92-015). There were no additional public comments received.
- 2. Response to General Comments**
- In general, the reviewers were complementary regarding the overall quality of the 1988 Proposed Guidelines. Several reviewers requested that the

Agency better define the focus and intended audiences and refine the Guidelines with regard to treatment of nonhuman exposure. The Agency has refined its approach and coverage in these Guidelines. Although these Guidelines deal specifically with human exposures to chemicals, additional supplemental guidance may be developed for ecological exposures, and exposures to biological or radiological entities. The Agency is currently developing separate guidelines for ecological risk assessment.

Concerns were expressed about the Agency's use of the terms exposure and dose. Consequently, the Agency reviewed its definitions and uses of these terms and evaluated their use elsewhere in the scientific community. The Agency has changed its definitions and uses of these terms from that in both the 1986 Guidelines and the 1988 Proposed Guidelines. It is believed that the definitions contained in the current Guidelines are now in concert with the definitions suggested by the National Academy of Sciences and others in the scientific field.

Many reviewers urged the Agency to be more explicit in its recommendations regarding uncertainty in statistics, limits of detection, censored data sets, and the use of models. Some reviewers felt the level of detail was appropriate for statistical uncertainty while others wanted additional methods for dealing with censored data. Several commended the Agency for its acknowledgement of uncertainty in exposure assessments and the call for its explicit description in all exposure assessments, while others expressed concern for lack of acknowledgement of model uncertainty. Accordingly, these areas have been revised and an entire section has been devoted to uncertainty. We agree with the reviewers that much more work remains to be done in this area, particularly with evaluating overall exposure assessment uncertainty, not only with models but also with the distributions of exposure parameters. The Agency may issue additional guidance in this area in the future.

Some reviewers submitted extensive documentation regarding detection limits and statistical representations. Several submitted comments arguing against data reporting conventions that result in censored data sets and recommended that the Agency issue a guidance document for establishing total system detection limits. The Agency found the documentation to be helpful and has revised the sections of the Guidelines accordingly. Unfortunately, several of the other suggestions go beyond the scope of this document.

The reviewers generally commented that the glossary was useful, presenting many technical terms and defining them in an appropriate manner. The glossary has been expanded to include the key terms used in the Guidelines, while at the same time correcting some definitions that were inconsistent or unclear. In particular, the definitions for exposure and dose have been revised.

3. Response to Comments on the Specific Questions

3.1. Should the 1988 Proposed Guidelines Be combined with the 1986 Guidelines?

The SAB and several other commentators recommended that the 1986 Guidelines and the 1988 Proposed Guidelines be combined into an integrated document. The Agency agrees with this recommendation and has made an effort to produce a single guideline that progresses logically from start to finish. This was accomplished through an extensive reformatting of the two sets of guidelines as an integrated document, rather than a simple joining together of the previous versions.

In integrating the two previous guidelines, the Agency has revised and updated the section in the 1986 Guidelines that suggests an outline for an exposure assessment. A more complete section (section 7 of the current Guidelines) now discusses how assessments should be presented and suggests a series of points to consider in reviewing assessments.

The Agency has also expanded the section in the 1986 Guidelines that discussed exposure scenarios, partly by

incorporating material from the 1988 Proposed Guidelines, and partly as a result of comments requesting clarification of the appropriate use of certain types of scenario (e.g., "worst case"). Section 5.3 of the current Guidelines extensively discusses the appropriateness of using various scenarios, estimates, and risk descriptors, and defines certain scenario-related terms for use in exposure assessments.

3.2. Is the Current State-of-the-Art in Making Measurements of Population Activities for the Purpose of Exposure Assessment Advanced to the Point Where the Agency Can Construct Guidelines in This Area?

Both the SAB and public comments recommended the inclusion of demographics, population dynamics, and population activity patterns in the exposure assessment process. In response, the Agency has included additional discussion on use of activity patterns in the current Guidelines, while recognizing that more research has to be done in this area.

3.3. Is the Level of Detail of the Guidelines Useful and Appropriate, Especially in the Area of Statistics?

As might be expected, there was no clear consensus of opinion on what constitutes appropriate coverage. Regarding quality assurance (QA) and quality control (QC), it was felt that a strong statement on the need for QA/QC followed by reference to appropriate EPA documents was a suitable level of detail. Statistical analyses, sampling issues, limit of detection, and other analytical issues all elicited many thoughtful comments. Where the recommendations did not exceed the scope of the document or the role of EPA, the Agency has attempted to blend the various recommendations into the current Guidelines. In all these areas, therefore, the previous sections have been revised in accordance with comments.

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**Friday
May 29, 1992**

Part VII

Department of Agriculture

Forest Service

36 CFR Part 242

Department of the Interior

Fish and Wildlife Service

50 CFR Part 100

**Subsistence Management Regulations for
Public Lands in Alaska; Final Rule**

DEPARTMENT OF AGRICULTURE**Forest Service****36 CFR Part 242****DEPARTMENT OF THE INTERIOR****Fish and Wildlife Service****50 CFR Part 100**

RIN 1018-AB43

Subsistence Management Regulations for Public Lands in Alaska, Subparts A, B, and C

AGENCY: Forest Service, Department of Agriculture. Fish and Wildlife Service, Department of the Interior.

ACTION: Final rule.

SUMMARY: This rule promulgates regulations governing administration of subsistence taking of fish and wildlife on public lands in Alaska. This rule implements the subsistence priority for rural Alaska residents under Title VIII of the Alaska National Interest Lands Conservation Act (ANILCA). It replaces the Temporary Subsistence Management Regulations for Public Lands in Alaska, which expire on June 30, 1992.

EFFECTIVE DATE: July 1, 1992.

FOR FURTHER INFORMATION CONTACT: Richard S. Pospahala, Office of Subsistence Management, U.S. Fish and Wildlife Service, 1011 E. Tudor Road, Anchorage, Alaska 99503; telephone (907) 786-3447. For questions specific to National Forest system lands, contact Norman R. Howse, Assistant Director Subsistence, USDA, Forest Service, Alaska Region, P.O. Box 21628, Juneau, Alaska 99802-1628; telephone (907) 586-8890.

SUPPLEMENTARY INFORMATION:**Background**

Title VIII of ANILCA (16 U.S.C. 3111-3126) requires the Secretary of the Interior and the Secretary of Agriculture (Secretaries) to implement a joint Federal Subsistence Management Program (FSMP) to grant a priority for subsistence uses of fish and wildlife resources on public lands in Alaska, unless the State of Alaska enacts and implements laws of general applicability consistent with sections 803, 804, and 805 of ANILCA. To be consistent with sections 803, 804, and 805 of ANILCA, the State's laws of general applicability must confine the preference for subsistence uses to those subsistence uses engaged in by rural Alaska residents. Until recently, the State managed the subsistence program on

public lands pursuant to section 805 of ANILCA. In December 1989, the Alaska Supreme Court ruled in *McDowell v. State of Alaska* that the rural preference found in the State subsistence statute violated the Alaska Constitution. The effect of this ruling required the State to delete the rural preference from its subsistence statute, and therefore, the State subsistence statute failed to comply with Title VIII of ANILCA. The Court stayed the effect of the *McDowell* decision until July 1, 1990.

Consequently, the Secretaries assumed responsibility for the implementation of Title VIII of ANILCA on July 1, 1990. On June 29, 1990, the "Temporary Subsistence Management Regulations for Public Lands in Alaska, Final Temporary Rule" were published in the *Federal Register* (55 FR 27114-27170). The temporary regulations defined and implemented a program approved by the Secretaries and administered by the Federal Subsistence Board (Board). Under the temporary regulations, the Secretary of the Interior with the concurrence of the Secretary of Agriculture appointed the Board Chair. Other members of the Board include the Alaska Regional Director, U.S. Fish and Wildlife Service; the Alaska Regional Director, National Park Service; the Alaska State Director, Bureau of Land Management; the Alaska Area Director, Bureau of Indian Affairs; and the Alaska Regional Forester, USDA Forest Service. These agencies participated in the development of the temporary regulations. In addition, all Board members have reviewed this final rule and concur in its publication. Because this final rule relates to public lands managed by an agency or agencies in both the Departments of Agriculture and the Interior, identical text will be incorporated into 36 CFR part 242 and 50 CFR part 100.

Summary of Comments

The proposed rule for Subsistence Management Regulations on Federal Public Lands in Alaska, subparts A, B, and C (57 FR 3676-3687, January 30, 1992) afforded the public a comment period of 45 days to address issues and language included therein. During the comment period, public meetings were held in Alaska in Anchorage, Barrow, Bethel, Dillingham, Fairbanks, Kodiak, Kotzebue, Naknek, Nome, and Sitka. In addition to comments offered during this comment period, comments received at 42 public hearings held for discussion regarding the draft Environmental Impact Statement (EIS), and at six public hearings on subpart D, were considered. The public submitted a total

of 446 written comments and 200 oral comments.

Analysis of Comments**Section 1 Purpose**

No comments were received on this section.

Section 2 Authority

Several commentors questioned the need for any regulation of subsistence taking of fish and wildlife. Title VIII of ANILCA provides for the continuation of the opportunities for subsistence uses, by rural Alaska residents, consistent with maintaining healthy fish and wildlife populations. The Secretaries' responsibilities are thus two-fold: To conserve healthy fish and wildlife populations and to ensure that non-wasteful subsistence uses of fish and wildlife populations are accorded priority over other consumptive uses on public lands. Section 814 of ANILCA requires the Secretaries to prescribe regulations as necessary to carry out these responsibilities. In accordance with the mandate of Title VIII of ANILCA, it is the intent of the Secretaries to regulate subsistence taking of fish and wildlife in such a way as to cause the least adverse impact possible on subsistence users.

It also was suggested that the regulations should not apply in cases of dire need. Emergency taking of wildlife in life-threatening situations is governed under State regulations; such taking is not prohibited under FSMP regulations.

Another commentor declared that management of fish and wildlife should only fall under the State's administration. The Secretaries agree that it is preferable for the State of Alaska to manage the subsistence taking and use of fish and wildlife. However, if the State regulatory regime is inconsistent with sections 803, 804, and 805 of ANILCA, then the Secretaries must establish a regulatory regime for public lands that meets those requirements. At this time, the State does not have a law of general applicability that is consistent with the title VIII requirement to grant a subsistence priority to residents of rural areas. As long as the State fails to satisfy section 805 of ANILCA, and as long as the rural preference is required by title VIII of ANILCA, the Secretaries must regulate subsistence taking and use of fish and wildlife on public lands. However, the regulations do provide for the State to reacquire the responsibility for managing subsistence taking of fish and wildlife on public lands.

Section 3 Applicability and Scope

Several commentors objected to the prohibition against subsistence taking in Glacier Bay National Park and Katmai National Park. Title II of ANILCA specifies the National Park Service areas in which subsistence uses are authorized. Title II does not authorize subsistence uses in Glacier Bay National Park, Katmai National Park, Kenai Fjords National Park, and that portion of Denali National Park established as Mt. McKinley National Park prior to passage of ANILCA. Therefore, neither Title VIII of ANILCA nor these regulations permit subsistence uses on the public lands identified above.

Several commentors expressed frustration with the lack of clarity in the regulations. Commentors generally did not identify the specific regulations that they thought were confusing. However, where possible, regulatory language has been revised to improve clarity. One commentor requested clarification of the meaning of the § 3(a) statement that these regulations do not supersede other agency specific regulations. This statement means that regulations in this final rule do not override regulations that individual agencies establish to carry out their particular responsibilities.

One commentor asserted that the regulations do not apply to a sovereign nation. The regulations apply to the taking of fish and wildlife resources on public lands as defined in this Part.

Another commentor suggested that the term "fish and wildlife" be replaced with the term "other wild and renewable resources," the term used in section 803 of ANILCA to define subsistence uses. ANILCA requires the Secretary to take over subsistence management responsibilities on public lands if the State fails to enact laws of general applicability consistent with sections 803, 804, and 805 of ANILCA. Section 805(d) of ANILCA specifies that these regulatory responsibilities apply to the taking of fish and wildlife on public lands. The FSMP has been established to assume these responsibilities until the Secretaries certify that the State's subsistence legislation complies with title VIII of ANILCA and a rulemaking proceeding to repeal these regulations has been completed. Additionally, section 1314 (a) and (b) of ANILCA further limit the State's subsistence management jurisdiction to fish and wildlife only, and ensure that management responsibility for all other resources remains with the Secretaries. Consequently, the FSMP pertains only to the taking of fish and wildlife on public

lands. The taking and use of wild and renewable resources, other than fish and wildlife, will continue to be managed by the appropriate land management agency.

Section 3 of these regulations specifies that the regulatory language applies to all non-navigable waters located on all public lands and to navigable waters located on certain public lands listed at § 3(b). The areas in this list, along with the area referred to as the Old Kuskokwim Wildlife Refuge which has now been deleted from this list in the final rule, previously appeared at various locations throughout § 24 of subpart D in the proposed regulations (56 FR 64404-64444). The area identified as the Old Kuskokwim Wildlife Refuge is that portion of the present Yukon Delta National Wildlife Refuge formerly known as the Kuskokwim National Wildlife Range. The definition of public lands found in ANILCA and these regulations does not include the submerged lands beneath navigable waters in the area formerly known as the Kuskokwim National Wildlife Range because the United States does not hold title to those submerged lands. As indicated in § 3(c), the areas in this list remain subject to modification through rulemaking procedures. Nothing in these regulations is intended to enlarge or diminish the Federal government's authority to manage submerged lands title to which is held by the United States. The Departments retain the authority to exercise jurisdiction over those submerged lands which the United States reserved at the time of Alaska's Statehood and which have not been subsequently conveyed to the State or any other party.

Section 4 Definitions

Comments on definitions included requests for clarity, criticisms of specific definitions, suggested revisions to specific definitions, and requests for additional terms to be defined. Several editorial changes have been made to correct inadvertent deletions and to clarify intent. Where possible, definitions have been revised to be more explicit. The definition of agency has been expanded to identify the five principal Federal land management agencies with subsistence management responsibilities.

The definitions of barter and customary trade elicited numerous comments. Some commentors objected to the regulation defining customary trade as an alternative means of supporting subsistence needs. They viewed customary trade as integral to, not an alternative to, subsistence, citing

section 803 of ANILCA. The final regulation has been amended to reflect this comment.

Several commentors felt that it was inappropriate to prohibit the use of money as a component of barter. Others mentioned that the definition of barter, which prohibits exchange of money, conflicts with the definition of customary trade, which authorizes the exchange of money as long as the exchange does not constitute a significant commercial enterprise. The definition of barter in the regulations, including the prohibition against use of cash, comes directly from section 803(2) of ANILCA. Likewise, the legislative history of ANILCA pertaining to customary trade reveals that cash may play a role in subsistence activities, and ANILCA accommodates that role. Several commentors recommended that the regulations establish more definitive guidelines describing exactly what constitutes customary trade. Some of these commentors suggested that the regulations use a dollar figure to define customary trade. Others felt that customary trade should be limited to the types and volumes of trade that occurred prior to the passage of ANILCA. At this time, insufficient customary and traditional use information exists to establish further guidelines that will accommodate subsistence use for customary trade while precluding the development of any significant commercial enterprise under the guise of subsistence. Following the enactment of this rule, the Board will place a high priority on refining the definition of customary trade and developing a definition for significant commercial enterprise, after considering recommendations submitted by the Federal Regional Advisory Councils (Regional Councils).

Several comments were received relative to the definitions of conservation of healthy populations of fish and wildlife and conservation of natural and healthy populations of fish and wildlife. Some felt that the definitions should be compatible with the State's sustained yield concept. Others saw the need to replace the definitions with a continued viability standard as found in sections 802, 804 and 816 of ANILCA. A few commentors wanted to reword the regulation to characterize subsistence uses as an integral, rather than natural, part of the ecosystem. Some commentors felt that the definition of natural and healthy populations of fish and wildlife was an unnecessarily conservative standard. A few commentors suggested that

managing for stable populations is unrealistic.

Title VIII sets forth, in sections 802(1) and 815(1), the term conservation of healthy fish and wildlife populations, rather than sustained yield, as the standard by which subsistence taking and uses will be managed. The definition of this term comes from Senate Report 96-413, p.233. The term conservation of natural and healthy populations of fish and wildlife has been deleted from the definitions section because adequate protection of natural populations in National Park Service areas is embodied in the conservation of healthy populations of fish and wildlife definition, which states that management will differ depending upon specific agency mandates.

Several commentors pointed out that the term continued viability was used in the regulations, but was not defined. A definition is unnecessary since the added protection afforded by conservation of healthy populations of fish and wildlife will also protect and assure the continued viability of those populations.

The definition of customary and traditional use was criticized as lacking a reference to the concept of sharing. Section 803 of ANILCA and these regulations include sharing in the definition of subsistence uses. Sharing is recognized as a characteristic of subsistence uses, and is one of eight factors to be used by the Board in making customary and traditional use determinations. Section _____.16 of these regulations describes the process the Board will employ when making customary and traditional use determinations. One commentor felt the last sentence of the regulation, referring to the important role of customary and traditional use in the economy of the community, was redundant.

One commentor felt that the definition of family was too restrictive because it excludes members of the extended family living in other households. Section 803(1) of ANILCA explicitly limits the definition of family to those persons related by blood, marriage, or adoption or those persons living within the same household on a permanent basis. Therefore, although members of an extended family may live in separate households, the members nevertheless satisfy the definition of family if they are related by blood, marriage, or adoption. The regulations recognize the importance of sharing, and do not prohibit the customary and traditional sharing of fish and wildlife for personal or family consumption.

Numerous comments were received concerning the definitions of Federal

lands and public lands. All of these comments focused on the issue of jurisdiction over fisheries in navigable waters. Many felt that the definitions should include navigable waters to protect subsistence use and the subsistence priority. They strongly believe it was Congress' intent to protect subsistence rights as broadly as possible. Additionally, many individuals commented that most subsistence resources are found in navigable waters.

The scope of these regulations is limited by the definition of public lands, which is found in section 102 of ANILCA and which only involves lands, waters, and interests therein title to which is in the United States. Because the United States does not generally own title to the submerged lands beneath navigable waters in Alaska, the public lands definition in ANILCA and these regulations generally excludes navigable waters.

Consequently, neither ANILCA nor these regulations apply generally to subsistence uses on navigable waters. However, based upon specific pre-Statehood reservations of submerged lands, § _____.3(b) establishes that these regulations apply to navigable waters located on the identified public lands. The listed areas remain subject to change through further rulemaking pending a review and determination of pre-Statehood reservations by the United States.

Some commentors requested that the terms reasonable opportunity, subsistence priority, and rural subsistence priority be defined. However, the definitions section is intended to provide definitions for terms that are used in the regulations; and because these terms do not occur in the regulations it is not necessary to define them.

Comments relating to the definition of resident consisted of opinions on what should constitute the minimum period of residency to qualify as a resident. The FSMP will continue to use the variety of factors listed in the regulations as the basis for determining who is a resident, because Board use of the various factors injects fairness and good faith into the process of identifying a resident.

Several requests suggested changes to the definition of subsistence uses. These regulations have adopted the term as defined by Congress in section 802 of ANILCA, and will not be amended.

Section _____.5 Eligibility for Subsistence Use

Three types of comments were received relative to determining eligibility for subsistence use. Some wanted clarification regarding which

individuals are eligible. A few objected to the authority of the National Park Service, separate from the Board, to regulate eligibility for subsistence uses on National Park Service lands. Some suggested specifically excluding military personnel stationed in rural areas from eligibility for subsistence use.

This section briefly describes those individuals eligible to take fish and wildlife for subsistence purposes under these regulations and how their eligibility is determined. There are two tests for Board determinations of eligibility. The first is rural residency. Only residents of communities or areas that the Board has determined to be rural are eligible for the subsistence priority. The process the Board uses to make rural determinations is described in § _____.15 of these regulations. The second test for determining eligibility is customary and traditional use determinations. In making these determinations, the Board determines which rural communities or areas have customary and traditional use of specific fish stocks and wildlife populations. After these determinations have been made, only those rural communities or areas determined by the Board to have customary and traditional use of particular fish stocks or wildlife populations are eligible for subsistence use of those stocks or populations. The Board may determine which fish stocks or wildlife populations, if any, have been customarily and traditionally used by residents of military installations that the Board has determined to be rural. If the Board has not made a customary and traditional determination of a fish stock or wildlife population, then all Alaska rural residents as defined in § _____.4 are eligible for use of those stocks or populations.

In accordance with section 203 of ANILCA, eligibility for the subsistence use of resources in areas managed by the National Park Service is restricted to local rural residents in National Preserves and, where specifically permitted, in National Monuments and Parks. National Park Service regulations govern which communities or individual residents qualify as local rural residents for specific National Park Service areas.

In some cases it may be necessary to establish priorities for subsistence uses among qualified rural Alaska residents in order to protect the continued viability of a fish stock or wildlife population or to continue subsistence uses. In these cases allocation among qualified rural Alaska residents will be determined according to the regulatory language found herein at § _____.17,

which is consistent with § 804 of ANILCA.

Section 6 Licenses, Permits, Harvest Tickets, Tags and Reports

The provisions authorizing alternative permitting systems received a great deal of attention. During the development of this final rule, there was strong criticism of the harvest permitting and reporting mechanisms existing under the temporary regulations. People said that these mechanisms were incompatible with customary and traditional practices, including those associated with cultural and religious beliefs. For example, in some communities a few hunters are responsible for providing the bulk of the community's meat supply. The existing permitting systems offer no legal means to accommodate this practice. People encouraged the development of alternative mechanisms to accommodate this and other well-established customary and traditional practices. Federal managers realize that harvest is often not reported because of these incompatibilities, and the result is an absence of accurate harvest and biological information. In response to these concerns, the proposed regulations to this final rule included language allowing the Board to implement alternative permitting systems and harvest reporting. Most comments expressed support for the proposed alternative permitting systems. A few said that only the disabled should be allowed to designate another hunter.

Public response to the alternative permitting provision in the proposed regulations to this final rule elicited additional support for implementation of such systems. People spoke of the importance of providing for extended families or for those who cannot hunt, such as the handicapped or the elderly. They described instances where it is culturally inappropriate for a person to harvest alone or for personal use and where a community-based harvest is important for cultural and ceremonial purposes such as funerals, memorials, and potlatches. People also spoke of the need and willingness of local representatives to manage harvest permitting, enforcement, and data collection.

People suggested additional remedies to better accommodate subsistence uses. These remedies included eliminating licenses for subsistence, replacing licenses with identification cards, not charging fees for any license or permit, not requiring licenses or permits to be carried in the field or validated at the harvest site, allowing incidental and opportunistic take without permits, accommodating individuals with limited

comprehension of English, not requiring "sport" licenses of subsistence users, issuing licenses according to the regulatory year rather than calendar year, and making permits more available by using vendors or local governmental entities for distribution. These issues will be considered as the FSMP develops.

Many people expressed concerns about enforcement problems, abuses of permits, and difficulties resulting from separate State and Federal licensing, permit, and reporting requirements. To the extent possible, these regulations are designed to work in conjunction with State requirements. Whenever possible, a State license, reporting, or permit mechanism will be used. Where State regulations regarding licenses, reporting or permits are inadequate, Federal license, reporting or permit mechanisms may, if necessary, provide rural Alaska residents subsistence opportunity while conserving healthy populations of fish and wildlife.

Some comments addressed the text of the regulations. There were requests to clarify the responsibilities of individuals and communities. People noted that modifiers such as immediately and at all times were excessively demanding and should be eliminated. People suggested that revocation of permission should be outlined and that tags be required for community bag limits. It was also suggested that there be stipulations that community harvest may only be permitted where all who wish to hunt can be allowed to participate. In response to these comments, the regulations have been revised to further clarify responsibilities and requirements.

Specific conditions for the use of a particular harvest reporting system may be applied on a case-by-case basis. Further development and refinement of guidelines for alternative permitting systems will occur as the FSMP evolves.

Although these regulations generally permit an individual to harvest wildlife during a particular season and at a specified level or bag limit, they also may permit harvest activity by a community. These regulations at § 6 were modified to state that intent more clearly: A defined group such as a community or a subunit of that community, such as a family, household, or traditional group, may be allowed to harvest under specific conditions.

Some commented that various harvest activities permitted by these regulations may violate section 815(1) of ANILCA, which prohibits transfer of subsistence privileges from one individual to another. These regulations do not

provide for such a transfer. Where alternative permitting systems are authorized for customary and traditional subsistence uses that involve more than an individual, the permits are for the whole activity and cannot be reassigned from one individual to another. It is the policy of the FSMP to cause the least adverse impact possible on rural residents that depend on subsistence resources, consistent with the sound management and conservation of healthy populations of fish and wildlife. The permit mechanisms of these regulations provide an opportunity for varied customary and traditional practices of subsistence uses and simultaneously provide for sound management of the resource.

Section 7 Restriction on Use

One commentor requested that the term "sharing" be specified along with customary trade and barter as an exception to the restrictions on subsistence uses. Sharing is not prohibited by this section. The intent of this section is to preclude non-subsistence exchange of items by limiting the exchange of fish and wildlife to barter or customary trade.

Another commentor requested that this section specify that subsistence users are not exempt from any prohibitions concerning controlled substances and requested that this section include a prohibition against substance abuse while engaging in subsistence activities. Regulations in this part address the taking and use of fish and wildlife on public lands in Alaska. They do not regulate controlled substances. Other statutes and regulations govern use of controlled substances.

Section 8 Penalties

Most comments focused on the appropriateness of the penalties. Some people thought the penalties were excessive, while others felt they were too small. Others suggested that the regulations should authorize enforcement authorities to seize property. Although these regulations address the taking and use of fish and wildlife on public lands, they do not provide a penalty provision separate from, or in addition to, the penalty and forfeiture provisions of each individual land managing agency. Rather, any person convicted of violating any provision of these regulations may be punished in accordance with the maximum penalty and forfeiture provisions of the agency managing the area where the violation occurred. Each individual land managing agency has its

own penalty and forfeiture provisions. The maximum penalty for any violation of these regulations committed on public lands may vary among the agencies.

One commentator was concerned that enforcement of regulations would be overzealous. The intent of the regulations is to maintain healthy fish and wildlife populations and provide continued opportunities for subsistence uses. Enforcement will be subject to agency policies and discretion.

Section 9 Information Collection Requirements

This section is included to comply with the requirements of the Paperwork Reduction Act. It contains information regarding the estimated times involved in complying with the requirements necessary to submit information required by these regulations. Some commentators felt that the time requirements listed were too low. As indicated in § 9(b) of this final rule, comments regarding time estimates should be sent directly to the address listed in this section.

Section 10 Federal Subsistence Board

Many of the comments relative to the Federal Subsistence Board pertained to the membership. People generally wanted subsistence users to have as great an effect as possible on decisions, and thus recommended that the Board have subsistence users as members. In particular, many people felt that the regulations should reflect the Board composition described in Alternative III of the EIS, in which the voting membership would include the Chairs of each Regional Council. It was also suggested that a Native person or a tribal representative be appointed to the Board. The administrative structure established by these regulations enables rural Alaska residents who have personal knowledge of local conditions and requirements to have a meaningful role in the management of fish and wildlife and of subsistence uses on public lands. The framework erected in § 11 and 12 of these regulations defines the mechanisms for including rural Alaska residents in the decisionmaking process, and establishes guidelines for decisionmakers when considering recommendations. Neither ANILCA nor these regulations provide mechanisms for including rural Alaska residents beyond the scope of the advisory system.

People were concerned that Board members lack sufficient knowledge, particularly of subsistence, to fulfill title VIII responsibilities adequately. One person listed several professional and

subsistence experience standards he felt the regulations should require individuals to satisfy in order to qualify for Board membership. The FSMP does afford rural Alaska residents the opportunity to submit recommendations for consideration to the Board. The advisory system found in these regulations at § 11 provides authority for the Board to accept and consider recommendations regarding subsistence uses and explains the procedures for responding to those recommendations. The State liaison and Regional Council liaisons may attend public portions of Board meetings and be actively involved as consultants to the Board. Additionally, Board members are supported by a variety of advisors and staff members who have professional and/or subsistence experience and education.

Commentors also suggested that the regulations be amended to include the Regional Forester as a voting member of the Board, and the State representative and Regional Council Chairpersons as liaisons to the Board. These omissions from the proposed rule were inadvertent; the final rule has been amended.

Co-management and delegation of management authority to regional or local entities were suggested by several commentors. Local entities mentioned included Indian Reorganization Act (IRA) councils, traditional councils and tribal governments. The Alaska Eskimo Whaling Commission was cited as an example of successful co-management. Because ANILCA does not authorize the Secretaries to delegate their title VIII responsibilities to private persons or groups, these regulations do not authorize the Board to delegate such responsibilities to private persons or groups.

However, regulatory language at § 10(d)(4)(xv), which is consistent with section 809 of ANILCA, authorizes the Board to enter into other cooperative agreements with other entities to effectuate these regulations. It is the intent of the FSMP to seek opportunities, within funding constraints, to cooperate with groups having an interest in subsistence management.

One commentator said that the regulations should include language giving the Board authority to assert jurisdiction off public lands for migratory species, such as caribou, to protect subsistence uses. These regulations implement the statutory provisions found in title VIII of ANILCA. Because title VIII of ANILCA only provides statutory authority for the Secretaries to exercise jurisdiction on

public lands, these regulations do not address activities off public lands.

Several comments suggested the regulations stipulate that Board meetings be held more than once per year and in locations, particularly rural areas, other than Anchorage. The final regulation has been revised to require a minimum of two meetings per year. Efforts will be made to hold Board meetings in locations other than Anchorage, subject to funding and time constraints.

Some people requested that § 10(d)(4)(ii), pertaining specifically to the Board's responsibility to determine rural areas, include a requirement for the Board to use recommendations from the Regional Councils in making these determinations. Section 10(e) of these regulations already obligates the Board to consider recommendations from Regional Councils regarding rural determinations. Additional regulatory language requiring the Board to consider such recommendations would be redundant.

These regulations authorize the Board to eliminate the taking of fish and wildlife on public lands for administrative reasons. Two commentors requested that the regulations further clarify what constitutes administrative reasons for closure. An administrative reason for closure could arise in a situation where unanticipated circumstances such as inclement weather cause the absence of agency law enforcement officers who would manage and regulate the subsistence harvest of a wildlife population. In such a case, the taking of the particular wildlife population on public lands would be prevented until agency officials become available.

Several commentors expressed concern regarding the Federal Advisory Committee Act (FACA) requirement that Regional Council and Federal Local Advisory Committee (Federal Advisory Committee) members be appointed by the Secretaries rather than elected by rural Alaska residents. One commentator requested that the requirement in § 10(d)(4)(xii) to appoint Federal Advisory Committee members pursuant to the FACA be revised to allow election of members by local residents pursuant to § 805 of ANILCA. FACA is a Federal statute which controls the procedures for appointing advisory committee representatives and are not subject to amendment by these regulations. It is the Board's intent to give rural Alaska residents as much control as possible over the selection of their representatives within the

constraints established by FACA. Accordingly, the Secretaries will appoint Regional Council members and Federal Advisory Committee members if such committees are formed by the Federal government, based upon nominations submitted to the Board.

Several commentors requested that § 10(d)(4)(xv) be amended to specify that tribal governments, IRA councils, and traditional councils be specifically listed as organizations with which the Board may enter into cooperative agreements. The final rule has been amended to clarify that the Board or agencies may enter into agreements with these as well as other entities. One commentor requested that international entities be specifically mentioned as eligible for entering into cooperative agreements with the Board. This provision was included in the proposed rule and remains in the final rule.

Several commentors suggested that contracting authority be specifically mentioned in the final rule. Contracting authority falls within the scope of cooperation authorized by section 809 of ANILCA and is provided for in § 10(d)(4)(xv) of the final rule.

Numerous commentors requested that more than eight subsistence resource regions be established. In response to public concerns over the eight regions envisioned in the EIS and the proposed rule, the Board recommended, and the Secretaries approved in the Record of Decision (ROD), the establishment of ten regions. This amendment is reflected in the final rule. Public comments received on the proposed regulations to the final rule do not reveal objections to adopting the ten regions as approved in the ROD. Therefore, this final rule includes a provision for the establishment of ten regions.

Several comments addressed the structure and function of the staff committee. Comments requested that the staff committee structure include subsistence users and that the State and other entities be invited to staff committee meetings. One commentor suggested that the regulations more clearly define the role of the staff committee to ensure that the staff committee does not exceed its authority. The role of the staff committee is to provide analytical and administrative support to the Board, at the direction of the Board. The staff committee envisions coordination with non-Federal entities to help fulfill these responsibilities. However, the primary avenue for involving rural Alaska residents in subsistence management will be through the Regional Councils and Federal Advisory Committees, if

established, described in §§ 11 and 12 of these regulations.

Several commentors wanted assurance that the Board would be responsive to Regional Council recommendations. Consistent with ANILCA, § 10(e) of these regulations specifically requires the Board to consider recommendations of the Regional Councils. The Board may choose not to follow recommendations that lack the support of substantial evidence, violate recognized principles of fish and wildlife conservation, or would be detrimental to the satisfaction of subsistence needs. The Board intends to use the Regional Councils to the maximum extent possible to fulfill its obligation to provide rural Alaska residents with a meaningful role in subsistence management, as mandated by Title VIII of ANILCA. Several commentors also suggested that the regulations direct the Board to respond, in writing and in a timely fashion, to Regional Council recommendations. The final rule has been amended to incorporate this suggestion.

Section 11 Regional Advisory Councils

Approximately half of the comments concerning the Regional Councils referred to the method of selection or requirements for Regional Council members. Most of these comments sought assurance that rural residency or subsistence uses would be a requirement for membership. Section 801(5) of ANILCA requires the Regional Councils to be composed of "rural residents who have personal knowledge of local conditions and requirements." Therefore, § 11(b) of these regulations obligates the Board to solicit and accept nominations for Regional Council members from local entities including Federal Advisory Committees, IRA and Traditional Councils, city councils and other local organizations and individuals. The Secretaries will appoint members to each Regional Council from the pool of nominations submitted to the Board for each region. The ROD outlined a system wherein the number of members on a Regional Council will be determined by the Board and will vary from region to region, depending on the number and distribution of subsistence users in the region, the variety of subsistence resources used, and the nature and extent of management issues. Public comments received on the proposed regulations do not reveal any objections to this system described in the ROD. Therefore, the Board intends to adopt this system of determining the number of members on each Regional Council.

Adequate funding for the Regional Council system was a commonly expressed concern. Federal managers are aware that the Regional Councils' ability to function properly in the past has been hampered by lack of funding. The budgeting process through which funding is allocated is complex and involves many participants and many requests for funding. Consequently, the amount of funding allocated to the advisory system is subject to forces over which the FSMP generally has limited control. Federal managers will continue to work through the channels available to it to secure funding levels necessary to administer the program adequately.

Several people wanted assurance that the Regional Councils would consider information provided by all sources, not just Federal Advisory Committees, if established, or the existing State Advisory Committees. The FSMP contemplates that Regional Councils will consider information presented by all sources during the decisionmaking process.

Many comments expressed dissatisfaction that the Regional Councils would be subject to the FACA and suggested deletion of all references to it. Until Congress provides otherwise, Regional Councils are subject to the requirements of the FACA.

Several people questioned the Regional Councils' oversight responsibilities and authorities relative to the Advisory Committees. The Regional Councils' authorities identified in § 11 of these regulations correlate with section 805 of ANILCA. Section 805 of ANILCA characterizes the role of the Federal Advisory Committees as providing advice to, and assisting, the Regional Councils. As such, any Advisory Committees will serve as a source of information to the Regional Councils. Consistent with section 805 of ANILCA, § 11 of these regulations does not authorize the Regional Councils to assert authority over, monitor, or otherwise oversee the Advisory Committees.

Two commentors requested further delineation of the duties and qualifications of the Regional Coordinator positions. The Regional Coordinators will provide administrative and technical assistance to the Regional Councils. Qualifications for these positions will include sufficient technical and administrative skills and knowledge of subsistence uses to provide effective assistance to the Regional Councils.

It was suggested that language be added describing Regional Council authority to appoint three members of

each Subsistence Resource Commission. Regulatory language has been added at § _____.11(c)(1)(vii) describing the responsibility of a Regional Council to appoint members to the Subsistence Resource Commissions (Commissions) within a Regional Council's respective region. An additional suggestion sought definition of the other duties found at § _____.11(c)(2)(ii) of these regulations, the Board would require the Regional Councils to perform. At this time, it is difficult to predict what other duties may be necessary for the Regional Councils to perform. Generally, as set out in § _____.11 of these regulations, the Regional Councils will review, evaluate and make recommendations on any existing or proposed regulation, policy, or management plan, or any other matter relating to the subsistence taking of fish and wildlife within or affecting the regions they represent.

Section _____.12 Local Advisory Committees

Many of the comments received pertaining to Federal Advisory Committees dealt with the establishment of the committees. Some commentors wanted to have one Federal Advisory Committee per village. Others suggested using the existing State advisory committees. Consistent with ANILCA, § _____.12 of these regulations directs the Board to establish Advisory Committees as necessary, after determining that the existing State advisory committees do not adequately perform the local committee functions of providing advice to, and assisting, the Regional Councils in carrying out their responsibilities. The review of the existing advisory system, published in June 1991, concluded that the existing Advisory Committees were an adequate source of advice and assistance to the Regional Councils in carrying out the functions authorized by ANILCA. Consequently, the Board will not establish Federal Advisory Committees unless the existing State Advisory Committees are found to be inadequate, and in addition, Federal Advisory Committees are found to be necessary. The Board will establish Advisory Committees if the Board determines that Federal Advisory Committees are necessary and if, after notice and hearing, the Board determines that existing State advisory committees are not fulfilling the requirements of providing advice to, and assisting the Regional Councils, as provided in § _____.12. In such instances, § _____.11(c)(1)(xii) authorizes Regional Councils to provide recommendations to the Board on the establishment and membership of

Federal Advisory Committees. The number of communities represented by each Federal Advisory Committee, if established, would be determined on a case-by-case basis.

Other comments addressed the membership of any Federal Advisory Committees, if established. Some people thought members should be selected by residents of the area, and wanted Federal Advisory Committee members to be subsistence users. It was also suggested that local IRA or traditional councils serve as the Federal Advisory Committee or appoint the members. If the Board determines that Federal Advisory Committees are necessary, and that the State advisory committees are inadequate, Federal Advisory Committee members shall be selected in accordance with requirements of these regulations, FACA and guidance provided in ANILCA. It is contemplated that if the Board establishes Federal Advisory Committees, the members of such committees shall be appointed by the Secretaries, but the Secretaries shall select appointees from nominations submitted through the Board by Native and non-Native rural Alaska residents.

Several comments addressed the role of the Federal Advisory Committees.

Some people urged that the committees be given a more meaningful role. Suggestions ranged from authorizing the committees to propose regulations to allowing the committees to manage local fish and wildlife resources. State Local Advisory Committees, and Federal Advisory Committees should they be established, are authorized and indeed encouraged to submit regulatory proposals, as well as provide any other information that will facilitate the management of fish and wildlife and subsistence uses in their areas. As discussed in the section pertaining to the Board, the Board lacks authority to delegate its subsistence management authority to private persons or groups. However, § _____.10 of these regulations requires the Board to consider recommendations submitted through the advisory system regarding the management of fish and wildlife and subsistence uses on public lands.

Several people expressed confusion concerning the role of the Advisory Committees. The role of the Advisory Committees is to provide advice to, and assist, the Regional Councils in carrying out their responsibilities. Committees can submit proposals on any matters that concern subsistence management on public lands.

One person remarked that subsistence users do not have enough time to participate in the administrative

process. Federal subsistence managers are aware of the unique circumstances hindering rural residents' participation in decisionmaking. The decisionmaking process is complex, involving many participants and many procedures. Time constraints are a necessity if the Board is to make decisions in a timely manner. It is anticipated that the assistance provided by Federal Regional Coordinators, and further refinement of the regulatory process, will help rural Alaska residents participate fully and effectively in the administrative process.

Section _____.13 Board/Agency Relationships

Two commentors felt this section suggested that the Secretary of the Interior had abrogated his authority over Federal subsistence management to the Board. Section 814 of ANILCA vests the Secretaries with the responsibility for implementing Title VIII of ANILCA. The Secretaries have delegated promulgation and signature authority for regulations of Subparts C and D to the Board. This delegation does not constitute a delegation of the Secretaries' final authority over these, or other subparts, of this rule.

One commentor suggested that the regulations should more explicitly define the role of the National Park and Monument Subsistence Resource Commissions in relation to the FSMP. The commentor also questioned whether the Board has the authority to regulate subsistence hunting on National Park and National Monument lands, if the Subpart B regulations do not constitute a delegation of section 808 authority from the Secretary of the Interior to the Board. The Commissions, established pursuant to section 808 of ANILCA, have a very specific role in regard to seven national parks and national monuments managed by the National Park Service. The role of the Commissions is to devise a subsistence hunting program for the appropriate National Park or Monument. Administrative and technical support for the Commissions is the responsibility of the National Park Service. A Commission may make subsistence hunting program recommendations regarding issues as diverse as: eligibility criteria for qualifying as local rural resident users of a National Park or Monument, the relationship of visitor service developments to subsistence hunting, or seasons and bag limits in a National Park or Monument. Most of the issues addressed by the commissions are beyond the purview of the Board's authority regarding rural and customary and traditional eligibility, or seasons

and bag limits and methods and means. Recommendations of the Commissions will continue to be conveyed directly to the Secretary of the Interior. If approved by the Secretary, such recommendations will be implemented by any one of several appropriate means.

Because the Board sets seasons and bag limits and methods and means provisions for all public lands, including National Park Service lands, it is expected that the Commissions will take an interest in such actions that may affect subsistence hunting in National Parks and Monuments. As necessary, it is expected that the Commissions will express their recommendations on such actions to the Secretary.

Duties granted to the Commissions do not include a delegation of regulatory authority because the Commissions are advisory only. Therefore, the suggestion that section 808 of ANILCA could prohibit the Board from implementing regulations affecting national parks or monuments is incorrect.

A few commentors felt that this section suggested that the Secretaries had abrogated their authority over FSMP to the Board. Section 814 of ANILCA places responsibility for the proper implementation of Title VIII of ANILCA with the Secretaries. To simplify and localize the process for promulgating rural determinations, customary and traditional use determinations, seasons and bag limits, and methods and means provisions, the Secretaries have delegated administrative and signature authority for subparts C and D to the Board. As with any such internal departmental delegation, the Secretaries remain responsible, as statutorily charged, for the proper administration of the program.

One commentor requested that the final rule include a regulation requiring the agencies to determine the effects of habitat management programs and development activities on subsistence resources and uses, and avoid implementing programs that adversely affect subsistence resources and uses. Section 810 of ANILCA establishes the requirement and process for agencies to consider effects of proposed resource uses on subsistence uses. It is unnecessary to reiterate this process in the final rule.

One commentor requested that State and Federal research data shall be made available to the Regional Councils, Advisory Committees, and the Board. In accordance with section 805(b) of ANILCA, § 10(e)(2) of these regulations requires that appropriate technical assistance be provided to the Regional Councils.

Section 14 Relationship to State Procedures and Regulations

A few comments addressed the Board's authority over activities off public lands. One commentor said the Board's authority to restrict the taking of fish and wildlife as authorized by the State should apply only to public lands. Other commentors said the regulations should be revised to assert more authority off public lands. Title VIII of ANILCA only provides authority for the Secretaries to exercise jurisdiction on public lands. Accordingly, these regulations do not address activities off public lands.

One commentor wanted a regulation to require a meeting between the Chair of the Board and the State Board of Game. Another commentor suggested adding a statement requiring consultation with the State before any closure of public lands to non-subsistence hunting or fishing.

Section 14 of this final rule sets the appropriate tone and level of authority and cooperation for the FSMP. Representatives of the Board and staff committee may meet as needed with State Board and Alaska Department of Fish and Game personnel. In addition, a member of the Federal subsistence staff voluntarily attends all Board of Game and many Board of Fisheries meetings. Federal subsistence managers and staff from Federal agency field stations voluntarily work closely with the Alaska Department of Fish and Game regarding allocations, closures, or restrictions of any type and this cooperative effort is expected to continue.

A provision addressing recertification of State management of subsistence uses on public lands has been added to the final rule.

Section 15 Rural Determination Process

Many people wanted provisions allowing individuals, or groups of individuals, living in non-rural areas to have the opportunity to qualify for a subsistence priority. Sections 801(5), 802(1) and 803 of ANILCA and these regulations confine the eligibility for engaging in subsistence uses to rural Alaska residents.

There were many comments addressing the rural determination process. Some commentors thought that only Ketchikan, Anchorage, Fairbanks, and Juneau, the four communities cited in the legislative history as examples of non-rural communities, should be classified as non-rural, and thus no rural determination process would be necessary. Others felt that rural

determinations should be made by the Regional Councils.

Some commentors criticized specific components of the rural determination process. Several thought that community infrastructure and population size are irrelevant and should not be factors in making rural determinations. Others remarked that the proportion of the cash element of an area's economy was not a valid consideration.

Alternative and additional guidelines were suggested. One suggestion was to use a community or area's historical pattern of customary and traditional uses to assess whether its character is rural or non-rural. Another was to recognize that variations among regions make uniform application of the guidelines inappropriate. It was also suggested that the process incorporate consideration of relative abundance of local resources relative to community size.

Some people thought the process should explicitly exclude military installations, thereby rendering residents of those installations ineligible for a subsistence priority. Others wanted the FSMP to ensure that residents of military installations would not be excluded.

Rural determinations have been the subject of intensive review the last two years. The process outlined in the final rule provides an equitable and effective way to make rural determinations. In the future the Board will establish a cycle for reviewing rural determinations. The next review will occur following publication of the results of the next decennial census. However, the Board may reconsider rural determinations outside of the established schedule if special circumstances warrant such action.

To mitigate the effect of sudden loss of subsistence uses on those who previously were dependent on them, there will be a five year waiting period before a Board decision to change a community or area's status from rural to non-rural becomes effective.

Section 16 Customary and Traditional Use Determination Process

Since the inception of the FSMP in July 1990, it has become increasingly apparent that many of the customary and traditional use determinations adopted from the 1989-90 State regulations must be reassessed. The proposed rule listed, and solicited changes to, these customary and traditional use determinations. Although many proposals were received, no changes have been made to these determinations in the final rule at this

time. The absence of change results because the process the Board will use for making customary and traditional use determinations does not become effective until July 1, 1992, when this final rule is implemented. Determinations of customary and traditional use of fish and wildlife populations will be made by the Board after the Board reviews recommendations of the Regional Councils. The Board will soon begin reviewing and, where appropriate, revising customary and traditional use determinations. The Board will also make new customary and traditional use determinations. Some determinations are anticipated to change due to the addition of several communities classified as rural. The Board will consider requests received by March 16, 1992, in response to the proposed rule, as well as requests received in appeals brought under the temporary regulations. A proposed priority list and schedule for customary and traditional use determinations will be published soon.

Some of the comments pertaining to the customary and traditional use determinations process stressed the importance of public involvement. The primary concern was that the Board should rely heavily on comments from local subsistence users when it makes customary and traditional use determinations. The Board recognizes that suggestions from rural Alaska residents are valuable sources of information concerning customary and traditional use. Consequently, a high priority task for the Regional Councils, once they are established, will be to provide the Board with information, and recommendations, concerning customary and traditional uses, and their views about them, in their regions. The basic customary and traditional use determination process will not change from region to region; however, regional differences will be considered when implementing the process.

Some commentators stated that customary and traditional use determinations on National Park Service lands should be made on the same basis as those for other public lands. Commentors also said that subsistence uses on National Park Service lands should be managed just like all other public lands in Alaska. This is not possible. Section 203 of ANILCA explicitly directs that subsistence uses in National Monuments and Parks are allowed only where specifically permitted by ANILCA. In addition, ANILCA allows those local rural residents with a personal or family

history of subsistence uses within a National Park Service unit to continue to make such use of those areas.

Several commentators felt that customary and traditional use determinations should be made on an area basis rather than an individual species or community basis. People also suggested that any species within the area should be considered a subsistence resource. The legislative history of ANILCA clearly indicates that, with the exception of lands managed by the National Park Service, customary and traditional uses should be evaluated on a community or area basis, rather than an individual basis. It also indicates that the subsistence use of each wildlife population or fish stock must be identified. Consequently, the Federal process for customary and traditional use determinations will consider the customary and traditional use of each wildlife population or fish stock within a given area by the residents of that area. The customary and traditional use determination process followed by the Board will permit evaluation of each community to determine if it exhibits characteristics of a subsistence community.

Section _____.17 Determining Priorities for Subsistence Uses Among Rural Alaska Residents

One commentator said this section should address the Board's full scope of responsibilities pursuant to section 804 of ANILCA. The responsibilities in section 804 of ANILCA are two-fold. The first is to accord subsistence uses by rural Alaska residents a priority over other consumptive uses of fish and wildlife. This responsibility is the driving force behind the FSMP, and all regulations contained in this rule are intended to promote fulfillment of this responsibility. The second responsibility is to allocate among rural Alaska residents, when necessary to protect the continued viability of fish or wildlife populations or to continue subsistence uses of specific populations. Section _____.17 of these regulations establishes the regulatory structure for allocating priorities for subsistence uses among rural Alaska residents.

Several commentators remarked that consideration of "store-bought food" and proximity to grocery stores should not be considered "alternative resources" for the purposes of determining how to allocate among qualified rural Alaska residents. These comments will be considered as the process for allocating among rural Alaska residents is refined.

Several commentators suggested that the regulations should be revised to

strengthen the Board's obligation to solicit advice from Federal Advisory Committees, if established, and heed recommendations from Regional Councils. As discussed in the narratives pertaining to the sections on the Board and Regional Councils, these regulations are designed to satisfy Title VIII of ANILCA, including Board responsibilities relative to public involvement. Recommendations from Regional Councils regarding the allocation of subsistence uses among rural Alaska residents, under § _____.10, will be accepted and considered by the Board.

Section _____.18 Regulation Adoption Process

There were numerous comments pertaining to various aspects of the regulation adoption process. One of the most frequently made suggestions was that thirty days was too short a period for public review of proposals submitted to the Board. The regulations do not limit the review period to thirty (30) days. Rather, the regulations establish thirty (30) days as the minimum time period to be allotted for public review. Longer public review periods are permissible and will be provided when appropriate. The regulations have been revised to reflect this intent. A thirty day minimum time period was selected because it gives the Board the option of establishing a quarterly or semiannual schedule to adopt proposals. If the Board chooses to consider proposals on a quarterly or semiannual basis, a longer review period would not be feasible. The regulatory process has many phases, each requiring valuable time. In order to make decisions in a timely fashion and at the same time fulfill these requirements, each phase of the decisionmaking process is often shorter than what would otherwise be desirable. Additionally, Federal managers are aware that rural Alaska residents in particular are especially susceptible to the consequences of short time frames. It is the intent of the FSMP to afford the public an adequate opportunity to review proposals. Language requiring the proposals to be made available for public comment has been added to the regulation.

Several people suggested that the Board stagger its consideration of proposals by species so that only certain species and certain groups of regulations would be considered at each Board meeting. While there presently is no need to adopt this strategy, the Board may consider such an approach in the future if the workload warrants it.

Some commentors wanted the regulations to allow proposals to be accepted by the Board all year long. Proposals on Subparts C and D may be submitted to the Board at any time of the year. However, unless there is a need to address a proposal immediately, proposals shall be routed through the established regulatory review cycle. The Regional Councils may develop proposals, and will review and evaluate proposals from other sources. Recommendations from Regional Councils shall be forwarded to the Board for action. Proposals from individuals, Federal or State agencies, or other groups shall be available to the Regional Councils for review and evaluation prior to action by the Board. The regulatory review cycle ensures that review and consideration of proposals is conducted in an efficient and thorough manner, with adequate review by agencies and the public. It is important that proposals go through this process unless other, more important concerns, such as protecting the health of the subject wildlife population or fish stock, have surfaced.

The list of customary and traditional use determinations has been moved to subpart C. This means that customary and traditional use determinations will not be reviewed on the same schedule as the seasons, bag limits, methods and means contained in subpart D. As described in the narrative regarding customary and traditional determinations (§ _____.16), proposals for changes to customary and traditional use determinations shall be addressed by the Board on a schedule that is different from the subpart D regulatory cycle. This schedule will be published.

Section _____.19 Closures and Other Special Actions

Several people requested assurance that the State of Alaska would be consulted in the event of a temporary closure. Consistent with section 816 of ANILCA, § _____.19(b) of these regulations has been revised to reflect that the Board consult with the State prior to any temporary closure of public lands to the subsistence use of a particular fish or wildlife population.

There were also suggestions to limit the Board's authority to close public lands only for reasons of public safety or to assure the continued viability of a particular fish or wildlife population. ANILCA identifies reasons for which closures of public lands may be made. These reasons include: (1) To assure the continued viability of a particular fish or wildlife population; (2) public safety; and (3) administration. Therefore, these regulations also include administration

as a reason for closing public lands to subsistence uses.

People suggested the regulations require individual agencies to notify the Board when they take action relating to subsistence uses. Effective lines of communication among agencies are well-established at all levels of the FSMP. Thus far there has arisen no need to establish a regulation directing agencies to formally notify the Board of their actions.

There were also suggestions to limit the Board's authority to close public lands only for reasons of public safety or to assure the continued viability of a particular fish or wildlife population. In an emergency situation, these regulations authorize the Board to direct an immediate closure for two reasons: (1) To assure the continued viability of a fish or wildlife population; or (2) for reasons of public safety. These regulations further identify three reasons for which the Board may direct temporary closures of subsistence uses on public lands: (1) To assure the continued viability of a particular fish or wildlife population; (2) for public safety; or (3) for reasons of administration. These regulations also provide that the Board may close public lands to non-subsistence uses when necessary to continue subsistence uses of fish and wildlife on public lands or when necessary for public safety, administration or to assure the continued viability of a particular fish or wildlife population.

People also wanted assurance that proposals dealing with emergency situations in which the health of fish or wildlife populations was in danger would be dealt with expeditiously. In carrying out their responsibility for conservation of healthy populations of fish and wildlife, the Board will assure that populations are not jeopardized.

In addition to revisions made in response to public comments, other modifications have been made to clarify the Board's closure and opening authorities. Consistent with section 815(3) of ANILCA, the regulations now specifically address the Board's authority to restrict non-subsistence uses on public lands. The regulations also clarify the Board's authority and responsibilities with regard to closures in emergency situations and in non-emergency situations. A new provision describes the Board's authority and responsibilities relative to opening or adjusting seasons, and increasing bag limits outside of the established regulatory cycle.

Section _____.20 Requests for Reconsideration

Several commentors opposed the proposed deletion of the provision authorizing the Board to stay its decisions. Section _____.20 provides the Board with sufficient mechanisms to act quickly, thereby eliminating the need for any stay provisions.

One commentor requested that the provision requiring information about how the requestor is adversely affected by the action be revised to require information about how the requestor or the subsistence resource or both are adversely affected by the action. The intent of this regulation is to provide people who are adversely affected by Board decisions with a mechanism for appealing that decision. If the health of a fish or wildlife population is threatened, the regulations in § _____.19 provide the mechanism for taking the appropriate actions.

Many comments suggested ways of reducing the burden on those individuals submitting requests for reconsideration. Some addressed the proposed forty-five day time limit for submitting requests for reconsideration. Several commentors requested that the time limit be extended, or deleted completely, because it was unfair to rural residents who often do not receive timely notice of Board decisions, and consequently do not have sufficient time to prepare the paperwork necessary for a request for reconsideration. The time limit to submit requests for reconsideration has accordingly been extended to sixty days.

One commentor suggested that petitioners only be required to submit a notice of grievance and a means of contacting the petitioner. Another commentor suggested that petitioners need to be reimbursed. Federal managers are aware of the unique circumstances that create obstacles to rural residents who would like to have the Board reconsider certain decisions. The Board will take into consideration these unique circumstances when considering requests for reconsideration. However, in order to make sound decisions, the Board needs the information that is outlined in the rule. Consequently, the final rule retains these information requirements. Additionally, there is no current legal authority for the Federal government to reimburse petitioners for their expenses.

One commentor also said the Board should be required to acknowledge that it has received a request for reconsideration, and request any additional information necessary, within

10 days of receipt of the request. The Board intends to acknowledge receipt of every request for reconsideration, and will request additional information as soon as possible following receipt of the request.

One commentor requested that the rule be amended to require the Board to accept and consider Regional Council recommendations on requests for reconsideration. Section _____.20(e) provides for this request.

One commentor identified a need to have an appeals process for situations where the allocation between State and Federal harvests is unfair to subsistence users. Section _____.19 of this final rule allows for the Board to make decisions outside of its decisionmaking cycle to accommodate situations in which there is a need for subsistence harvest. A provision allowing this to be accomplished with a request for reconsideration is not necessary.

In addition to the procedures described in this section, any person may petition for the issuance, amendment or repeal of a subpart A or B regulation under the provisions of 43 CFR part 14 and the Administrative Procedures Act. Petitions must identify the regulation being appealed or provide the text of a proposed rule, and include reasons in support of the petition. The petition must be addressed to the Secretary of the Interior, U.S. Department of the Interior, Washington, DC 20240.

One comment maintained that despite the existence of the request for reconsideration provision in the final rule, the regulatory language must provide procedures for the administrative resolution of subsistence-related disputes. To resolve disputes informally and without litigation, the FSMP affords subsistence users, and others, direct access to the Board through the request for reconsideration provision.

Section _____.21 [Reserved]

Section _____.22 Subsistence Resource Regions

Several comments were received relating primarily to Regional Council boundaries or configurations. After considering these comments, the Secretaries' decision in the ROD, and factors such as common cultural practices, similar resource use, distinct wildlife populations, recognizable regional boundaries, the need for local involvement, and cost effectiveness, the Board has established 10 Federal Subsistence Resource Regions as shown in the revised § _____.22 of this final rule.

Finally, one commentor wanted to know what is meant by the sentence following subpart C, Customary and Traditional Use Determinations, under the heading "Title 36-Parks, Forests and Public Property". The sentence reads "Part 242 of title 36 is proposed to be revised as set forth at the end of the common rule." This sentence is necessary for codification of regulations in the Code of Federal Regulations. It does not affect the content or implementation of Federal subsistence regulations.

Subpart D

This subpart will contain sections on definitions, prohibitions, methods and means, individual species seasons and bag limits, and fish and shellfish. It is not included in this rulemaking as it is being promulgated under a separate rulemaking process; however, it will be issued concurrently with subparts A, B and C as a final rule. Subparts A, B, C, and D will be codified in 36 CFR part 242 and 50 CFR part 100.

Conformance With Statutory and Regulatory Authorities National Environmental Policy Act Compliance Environmental Impact Statement

A draft Environmental Impact Statement (EIS) that described four alternatives for developing a Federal Subsistence Management Program in Alaska was distributed for public comment on October 7, 1991. That document described the major issues associated with Federal subsistence management as identified through public meetings, written comments and staff analysis and examined the environmental consequences of the four alternatives. Proposed regulations (subparts A, B, and C) that would implement the preferred alternative were included in the draft EIS as an appendix. They were subsequently published as a proposed rule in the *Federal Register* on January 30, 1992. The final EIS was published on February 28, 1992.

Based on the public comment received, the analysis contained in the final EIS, and the recommendations of the Board and the Department of the Interior's Subsistence Policy Group, it is the decision of the Secretary of the Interior, with the concurrence of the Secretary of Agriculture, acting through the Forest Service, to implement Alternative IV as identified in the final EIS with two modifications. The first modification is to increase the number of regions and Regional Councils from eight, as shown in the proposed action in the draft EIS, to ten. The second modification pertains to the rural

determination process. The change consists of including a five year waiting period for implementation of Board decisions to change community or area status from rural to non-rural. These regulations, after consideration of all timely public comments, implement the decision as documented in the ROD on Subsistence Management for Federal public lands in Alaska that was signed April 6, 1992.

Compliance with Section 810 of ANILCA

The intent of all Federal subsistence regulations is to provide opportunities for subsistence uses subject to the limitation of protecting healthy fish and wildlife populations. The section 810 analysis was completed as part of the final EIS process. The final section 810 analysis determination appears in the April 6, 1992 ROD. The section 810 evaluation concludes that the FSMP under alternative IV would have some local impacts on subsistence uses, but would not constitute a significant restriction of subsistence uses under the "may significantly restrict" standard.

Paperwork Reduction Act

These rules contain information collection requirements subject to Office of Management and Budget (OMB) approval under 44 U.S.C. 3501-3520. They apply to the use of public lands by rural Alaska residents for subsistence uses. The information collection requirements described above are approved by the OMB under 44 U.S.C. 3501 and have been assigned clearance number 1018-0075.

Economic Effects

Executive Order 12291, "Federal Regulation," of February 19, 1981, requires the preparation of regulatory impact analysis for major rules. A major rule is one likely to result in an annual effect on the economy of \$100 million or more; a major increase in costs or prices for consumers, individual industries, government agencies or geographic regions; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based enterprises. The Regulatory Flexibility Act (5 U.S.C. 601-612) requires preparation of flexibility analyses for rules that will have a significant effect on a substantial number of small entities, which include small businesses, organizations or governmental jurisdictions.

The Departments of the Interior and Agriculture have determined that this rulemaking is not a "major rule" within the meaning of Executive Order 12291.

and certify that it will not have a significant economic effect on a substantial number of small entities within the meaning of the Regulatory Flexibility Act.

This rulemaking will impose no significant costs on small entities; the exact number of businesses and the amount of trade that will result from this Federal land-related activity is unknown. The aggregate effect is an insignificant positive economic effect on a number of small entities. The number of small entities affected is unknown, but the fact that the positive effects will be seasonal in nature and will, in most cases, merely continue pre-existing uses of public lands indicates that they will not be significant.

These regulations do not meet the threshold criteria of "Federalism Effects" as set forth in Executive Order 12612. Title VIII of ANILCA requires the Secretaries to administer a subsistence preference on public lands. The scope of this program is limited by definition to public lands in Alaska. Likewise, these regulations have no significant takings implication relating to any property rights as outlined by Executive Order 12630.

Drafting Information

This regulation was drafted under the guidance of Richard S. Pospahala, of the Office of Subsistence Management, Alaska Regional Office, U.S. Fish and Wildlife Service, Anchorage, Alaska. Additional guidance was provided by John Borbridge, Bureau of Indian Affairs; Thomas H. Boyd, Bureau of Land Management; Bob Gerhard, National Park Service; Norman R. Howse, USDA Forest Service. The primary author was Susan K. Detwiler. Contributors were Peggy Fox, Sharon Fleek, Cheryl Cline, Bill Knauer, and Ron Thuma, U.S. Fish and Wildlife Service; John Hiscock, National Park Service; and Ken Thompson, USDA Forest Service.

List of Subjects

36 CFR Part 242

Administrative practice and procedure, Alaska, Fish, Public lands, Reporting and record keeping requirements, Subsistence, Wildlife.

50 CFR Part 100

Administrative practice and procedure, Alaska, Fish, Public lands, Reporting and record keeping requirements, Subsistence, Wildlife.

Words of Issuance

For the reasons set out in the preamble, subparts A, B, and C of part 242, title 36, and part 100, title 50 of the

Code of Federal Regulations, are revised as set forth below. The text of each subpart is identical.

PART _____—SUBSISTENCE MANAGEMENT REGULATIONS FOR PUBLIC LANDS IN ALASKA

Subpart A—General Provisions

Sec.

- ____.1 Purpose.
- ____.2 Authority.
- ____.3 Applicability and scope.
- ____.4 Definitions.
- ____.5 Eligibility for subsistence use.
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Subpart B—Program Structure

- ____.10 Federal Subsistence Board.
- ____.11 Regional advisory councils.
- ____.12 Local advisory committees.
- ____.13 Board/agency relationships.
- ____.14 Relationship to State procedures and regulations.
- ____.15 Rural determination process.
- ____.16 Customary and traditional use determination process.
- ____.17 Determining priorities for subsistence uses among rural Alaska residents.
- ____.18 Regulation adoption process.
- ____.19 Closures and other special actions.
- ____.20 Request for reconsideration.
- ____.21 [Reserved].

Subpart C—Board Determinations

- ____.22 Subsistence resource regions.
- ____.23 Rural determinations.
- ____.24 Customary and traditional use determinations.

Subpart A—General Provisions

§ _____.1 Purpose.

The regulations in this part implement the Federal Subsistence Management Program on public lands within the State of Alaska.

§ _____.2 Authority.

These regulations are issued pursuant to authority designated above, and specifically the authority vested in the Secretary of the Interior and Secretary of Agriculture specified in section 814 of the Alaska National Interest Lands Conservation Act (ANILCA) 16 U.S.C. 3124 (1980).

§ _____.3 Applicability and scope.

(a) The regulations of this part implement the provisions of Title VIII of ANILCA relevant to the taking of fish and wildlife on public lands in the State of Alaska. The regulations of this part do not permit subsistence uses in Glacier Bay National Park, Kenai Fjords

National Park, Katmai National Park, and that portion of Denali National Park established as Mt. McKinley National Park prior to passage of ANILCA, where subsistence taking and uses are prohibited. These regulations do not supersede agency specific regulations.

(b) The regulations contained in subpart D apply on all public lands including all non-navigable waters located on these lands. However, the regulations contained in subpart D do not authorize any subsistence uses in those National Parks listed in § _____.3(a). In the following areas, the regulations in subpart D apply on all Federal public lands including all waters located on these lands:

(1) The area beginning at a point on the boundary between the United States and Canada, on the divide between the north and south forks of the Firth River, approximate latitude 68°52' N., longitude 141°00' W., thence westerly along this divide and the periphery of the watershed northward to the Arctic Ocean, along the crest of portions of the Brooks Range and the DeLong Mountains, to Cape Lisburne;

(2) The area north of 61° north latitude, south of 61°21' north latitude, west of 163°40' longitude and east of the Bering Sea shoreline including Hazen Bay;

(3) Nunivak Island and waters of the Bering Sea within one mile of its shorelines;

(4) The area west of the eastern most tip of Unimak Island to the terminus of the Aleutian Islands, except the area between Akutan Pass and Samalga Island;

(5) Simeonof Island and all waters of the Pacific Ocean within one-mile of Simeonof Island;

(6) the Semidi Islands and all waters of the Pacific Ocean within one mile of each of the Semidi Islands;

(7) Kodiak National Wildlife Refuge;

(8) Waters of the Pacific Ocean enclosed by the boundaries of Womans Bay, Gibson Cove, and an area defined by a line one-half mile on either side of the mouth of Karluk River, and extending seaward 3,000 feet;

(9) All waters of the Pacific Ocean within 1,500 feet seaward of the shoreline of Afognak Island;

(10) Kenai National Wildlife Refuge;

(11) Glacier Bay National Preserve.

(c) The public lands described in § _____.3(b) (1)–(11) remain subject to change through rulemaking pending a Department of the Interior review of title and jurisdictional issues regarding certain submerged lands beneath navigable waters in Alaska.

§ 4 Definitions.

The following definitions apply to all regulations contained in this part.

Agency means a subunit of a cabinet level Department of the Federal government having land management authority over the public lands including, but not limited to, the U.S. Fish & Wildlife Service, Bureau of Indian Affairs, Bureau of Land Management, National Park Service, and USDA Forest Service.

ANILCA means the Alaska National Interest Lands Conservation Act, Public Law 96-487, 94 Stat. 2371 (December 2, 1980) (codified, as amended, in scattered sections of 16 U.S.C. and 43 U.S.C.).

Barter means the exchange of fish or wildlife or their parts taken for subsistence uses; for other fish, wildlife or their parts; or, for other food or for nonedible items other than money, if the exchange is of a limited and noncommercial nature.

Board means the Federal Subsistence Board as described in § 10 of this part.

Commissions means the Subsistence Resource Commissions established pursuant to section 808 of ANILCA.

Conservation of healthy populations of fish and wildlife means the maintenance of fish and wildlife resources and their habitats in a condition that assures stable and continuing natural populations and species mix of plants and animals in relation to their ecosystem, including the recognition that local rural residents engaged in subsistence uses may be a natural part of that ecosystem; minimizes the likelihood of irreversible or long-term adverse effects upon such populations and species; ensures the maximum practicable diversity of options for the future; and recognizes that the policies and legal authorities of the managing agencies will determine the nature and degree of management programs affecting ecological relationships, population dynamics, and the manipulation of the components of the ecosystem.

Customary and traditional use means a long-established, consistent pattern of use, incorporating beliefs and customs which have been transmitted from generation to generation. This use plays an important role in the economy of the community.

Customary trade means cash sale of fish and wildlife resources regulated herein, not otherwise prohibited by State or Federal law or regulation, to support personal and family needs; and does not include trade which constitutes a significant commercial enterprise.

FACA means the Federal Advisory Committee Act, Public Law 92-463, 86

Stat. 770 (October 6, 1972) (codified as amended, at 5 U.S.C. appendix II 1-15).

Federal Advisory Committees or Federal Advisory Committee means the Federal Local Advisory Committees as described in § 12.

Family means all persons related by blood, marriage or adoption, or any person living within the household on a permanent basis.

Federal lands means lands and waters and interests therein the title to which is in the United States.

Fish and wildlife means any member of the animal kingdom, including without limitation any mammal, fish, bird (including any migratory, nonmigratory or endangered bird for which protection is also afforded by treaty or other international agreement), amphibian, reptile, mollusk, crustacean, arthropod, or other invertebrate, and includes any part, product, egg, or offspring thereof, or the carcass or part thereof.

Game Management Unit or GMU means one of the 26 geographical areas listed under game management units in the codified hunting and trapping regulations and the Game Unit Maps of Alaska.

Person means an individual and does not include a corporation, company, partnership, firm, association, organization, business, trust or society.

Public lands or public land means lands situated in Alaska which are Federal lands, except—

(1) land selections of the State of Alaska which have been tentatively approved or validly selected under the Alaska Statehood Act and lands which have been confirmed to, validly selected by, or granted to the Territory of Alaska or the State under any other provision of Federal law;

(2) land selections of a Native Corporation made under the Alaska Native Claims Settlement Act which have not been conveyed to a Native Corporation, unless any such selection is determined to be invalid or is relinquished; and

(3) lands referred to in section 19(b) of the Alaska Native Claims Settlement Act.

Regional Councils or Regional Council means the Regional Advisory Councils as described in § 11.

Regulatory year means July 1 through June 30.

Resident means any person who has his or her primary, permanent home within Alaska and whenever absent from this primary, permanent home, has the intention of returning to it. Factors demonstrating the location of a person's primary, permanent home may include, but are not limited to: The address listed

on an Alaska license to drive, hunt, fish, or engage in an activity regulated by a government entity; affidavit of person or persons who know the individual; voter registration; location of residences owned, rented or leased; location of stored household goods; residence of spouse, minor children or dependents; tax documents; or whether the person claims residence in another location for any purpose.

Rural means any community or area of Alaska determined by the Board to qualify as such under the process described in § 15 of this Part.

Secretary means the Secretary of the Interior, except that in reference to matters related to any unit of the National Forest System, such term means the Secretary of Agriculture.

State means the State of Alaska.

Subsistence uses means the customary and traditional uses by rural Alaska residents of wild, renewable resources for direct personal or family consumption as food, shelter, fuel, clothing, tools, or transportation; for the making and selling of handicraft articles out of nonedible byproducts of fish and wildlife resources taken for personal or family consumption; for barter, or sharing for personal or family consumption; and for customary trade.

Take or taking as used with respect to fish or wildlife, means to pursue, hunt, shoot, trap, net, capture, collect, kill, harm, or attempt to engage in any such conduct.

Year means calendar year unless another year is specified.

§ 5 Eligibility for subsistence use.

(a) The taking of fish and wildlife on public lands for subsistence uses is restricted to Alaskans who are residents of rural areas or communities. Other individuals, including Alaskans who are residents of non-rural areas or communities listed in § 23, are prohibited from taking fish and wildlife on public lands for subsistence uses under these regulations.

(b) Where the Board has made a customary and traditional use determination regarding subsistence use of a specific fish stock or wildlife population, in accordance with, and as listed in, § 24, only those Alaskans who are residents of rural areas or communities so designated are eligible for subsistence taking of that population, on public lands for subsistence uses, under these regulations. All other individuals are prohibited from taking fish or wildlife from that population under these regulations.

(c) Where customary and traditional use determinations for a fish stock or wildlife population within a specific area have not yet been made by the Board (e.g. "no determination"), all Alaskans who are residents of rural areas or communities are eligible to participate in subsistence taking of that stock or population under these regulations.

(d) This section does not limit the authority of the National Park Service to regulate further the eligibility of those individuals qualified to engage in subsistence uses on National Park Service lands in accordance with specific authority in ANILCA, and National Park Service regulations at 36 CFR part 13.

§ 6. Licenses, permits, harvest tickets, tags, and reports.

(a) To take fish and wildlife on public lands for subsistence uses, subsistence users must possess and comply with the provisions of any pertinent permits, harvest tickets, or tags required by the State, or Federal permits, harvest tickets, or tags as required by the Board; and must possess the pertinent valid State hunting, fishing, and trapping licenses unless Federal licenses are required or unless otherwise provided for in these regulations.

(b) To make a fraudulent application for Federal or State licenses, permits, harvest tickets or tags is prohibited.

(c) Harvest tickets, tags, permits, or other required documents must be validated before removing the kill from the harvest site.

(d) Persons engaged in taking fish and wildlife under these regulations must comply with all reporting provisions which the Board may require.

(e) Licenses, permits, harvest tickets, tags or other documents required by this section must be produced by individuals upon the request of a State or Federal law enforcement agent. Persons engaged in taking fish and wildlife under these regulations must allow State or Federal law enforcement agents to inspect any apparatus designed to be used, or capable of being used to take fish or wildlife, or any fish or wildlife in possession.

(f) The Board may implement harvest reporting systems or permit systems where:

(1) The fish and wildlife is taken by an individual who is required to obtain and possess pertinent State harvest permits, tickets, or tags, or Federal permits, harvest tickets, or tags;

(2) A qualified subsistence user may designate another qualified subsistence user to take fish and wildlife on his or her behalf; or

(3) The fish and wildlife is taken by individuals or community representatives permitted a one-time or annual harvest for special purposes including ceremonies and potlatches;

(4) The fish and wildlife is taken by representatives of a community permitted to do so in a manner consistent with the community's customary and traditional practices.

(g) When the taking of fish and wildlife is in accordance with § 6, the permittee must comply with all of the reporting requirements of the permit. Individuals designated on a permit to take fish and wildlife are required to have that permit in their possession during the taking and to comply with all requirements of the permit, regulations in Subpart A § 6 pertaining to validation and reporting, and to regulations in Subpart D pertaining to methods and means, possession and transportation, and utilization.

(h) When a community takes fish and wildlife in accordance with § 6(f) (3) and (4), the harvest activity must be reported in accordance with regulations specified for that community in subpart D, and as required by any applicable permit conditions. Individuals may be responsible for particular reporting requirements in the conditions permitting a specific community's harvest. Failure to comply with these conditions is a violation of these regulations. Community harvests are reviewed annually under subpart D regulations.

§ 7. Restriction on use.

(a) When fish and wildlife are taken pursuant to these regulations, trade of the fish and wildlife, other than for customary trade or barter, is prohibited.

(b) When fish and wildlife are taken pursuant to these regulations, use or trade of the fish and wildlife which constitutes a significant commercial enterprise is prohibited.

§ 8. Penalties.

A person convicted of violating any provision of 50 CFR part 100 or 36 CFR part 242 may be punished by a fine or by imprisonment in accordance with the penalty provisions applicable to the public land where the violation occurred.

§ 9. Information collection requirements.

(a) These rules contain information collection requirements subject to Office of Management and Budget (OMB) approval under 44 U.S.C. 3501-3520. They apply to subsistence uses on public lands in Alaska.

(1) Section 20, Request for reconsideration. The information collection requirements contained in this section provide a standardized process to allow individuals the opportunity to appeal decisions of the Board. Submission of a request for reconsideration is voluntary but required to receive a final determination by the Board. The Department of the Interior estimates that a request for reconsideration will take 4 hours to prepare and submit.

(2) Section 6, Licenses, permits, harvest tickets, tags, and reports. The information collection requirements contained in this section provide for permit-specific subsistence activities not authorized through the general adoption of State regulations. These regulations require this information before a rural Alaska resident may engage in subsistence uses on public lands. The Department estimates that the average time necessary to obtain and comply with this permit information collection requirement is 15 minutes.

(3) The remaining information collection requirements contained in this part imposed upon subsistence uses are those adopted from State regulations. The information collection requirements must be satisfied before rural Alaska residents may engage in subsistence uses on public lands. The Department estimates that the average burden imposed upon individuals will be 8 minutes.

(b) Direct comments on the burden estimate or any other aspect of the burden estimate to: Information Collection Officer, U.S. Fish and Wildlife Service, 1849 C Street NW., MS 224 ARLSQ, Washington, DC 20240; and the Office of Management and Budget, Paperwork Reduction Project (1018-0075), Washington, DC 20503. Additionally, information requirements will be imposed when the Regional Councils, subject to the Federal Advisory Committee Act (FACA), are established under Subpart B. Such requirements will be submitted to OMB for approval prior to their implementation.

Subpart B—Program Structure

§ 10. Federal Subsistence Board.

(a) The Secretary of the Interior and Secretary of Agriculture hereby establish, and delegate responsibility for, administering the subsistence taking and uses of fish and wildlife on public lands, and the related promulgation and signature authority for regulations of Subparts C and D, contained herein, to the Board.

(b) Membership.

(1) The voting membership of the Board shall consist of a Chair to be appointed by the Secretary of the Interior with the concurrence of the Secretary of Agriculture; the Alaska Regional Director, U.S. Fish and Wildlife Service; Alaska Regional Director, National Park Service; Alaska Regional Forester, USDA Forest Service; the Alaska State Director, Bureau of Land Management; and the Alaska Area Director, Bureau of Indian Affairs. Each member of the Board may appoint a designee.

(2) [Reserved.]

(c) Liaisons to the Board shall consist of a State liaison, and the Chairpersons of each Regional Council. The State liaison and the Chairpersons of each Regional Council may attend public sessions of all Board meetings and be actively involved as consultants to the Board.

(d) Powers and Duties.

(1) Meetings shall occur at least twice per year and at such other times as deemed necessary by the Board. Meetings shall occur at the call of the Chair, but any member may request a meeting.

(2) A quorum shall consist of four members.

(3) No action may be taken unless a majority of voting members are in agreement.

(4) The Board is empowered, to the extent necessary, to implement Title VIII of ANILCA, to:

(i) Promulgate regulations for the management of subsistence taking and uses of fish and wildlife on public lands;

(ii) Determine which communities or areas of the State are rural or non-rural;

(iii) Determine which rural Alaska areas or communities have customary and traditional subsistence uses of specific fish and wildlife populations;

(iv) Allocate subsistence uses of fish and wildlife populations on public lands;

(v) Ensure that the taking on public lands of fish and wildlife for nonwasteful subsistence uses shall be accorded priority over the taking on such lands of fish and wildlife for other purposes;

(vi) Close public lands to the non-subsistence taking of fish and wildlife;

(vii) Establish priorities for the subsistence taking of fish and wildlife on public lands among rural Alaska residents;

(viii) Restrict or eliminate taking of fish and wildlife on public lands;

(ix) Determine what types and forms of trade of fish and wildlife taken for subsistence uses constitute allowable customary trade;

(x) Authorize the Regional Councils to convene;

(xi) Establish a Regional Council in each subsistence resource region and recommend to the Secretaries, appointees to the Regional Councils, pursuant to the FACA;

(xii) Establish Federal Advisory Committees within the subsistence resource regions, if necessary and recommend to the Secretaries that members of the Federal Advisory Committees be appointed from the group of individuals nominated by rural Alaska residents;

(xiii) Establish rules and procedures for the operation of the Board, and the Regional Councils;

(xiv) Review and respond to proposals for regulations, management plans, policies, and other matters related to subsistence taking and uses of fish and wildlife;

(xv) Enter into cooperative agreements or otherwise cooperate with Federal agencies, the State, Native corporations, local governmental entities, and other persons and organizations, including international entities to effectuate the purposes and policies of the Federal subsistence management program;

(xvi) Develop alternative permitting processes relating to the subsistence taking of fish and wildlife to ensure continued opportunities for subsistence; and

(xvii) Take other actions authorized by the Secretaries to implement Title VIII of ANILCA.

(5) The Board shall establish a Staff Committee composed of a member from the U.S. Fish and Wildlife Service, National Park Service, U.S. Bureau of Land Management, Bureau of Indian Affairs, and USDA Forest Service for analytical and administrative assistance. The U.S. Fish and Wildlife Service representative shall serve as Chair of the Staff Committee.

(6) The Board may establish and dissolve additional committees as necessary for assistance.

(7) The U.S. Fish and Wildlife Service shall provide appropriate administrative support for the Board.

(8) The Board shall authorize at least two meetings per year for each Regional Council.

(e) Relationship to Regional Councils.

(1) The Board shall consider the reports and recommendations of the Regional Councils concerning the taking of fish and wildlife on public lands within their respective regions for subsistence uses. The Board may choose not to follow any Regional Council recommendation which it determines is not supported by substantial evidence,

violates recognized principles of fish and wildlife conservation, would be detrimental to the satisfaction of subsistence needs, or in closure situations, for reasons of public safety or administration or to assure the continued viability of a particular fish or wildlife population. If a recommendation is not adopted, the Board shall set forth the factual basis and the reasons for the decision, in writing, in a timely fashion.

(2) The Board shall provide available and appropriate technical assistance to the Regional Councils.

§ 11 Regional advisory councils.

(a) The Board shall establish a Regional Council for each subsistence resource region to participate in the Federal subsistence management program. The Regional Councils shall be established, and conduct their activities, in accordance with the FACA. The Regional Councils shall provide a regional forum for the collection and expression of opinions and recommendations on matters related to subsistence taking and uses of fish and wildlife resources on public lands. The Regional Councils shall provide for public participation in the Federal regulatory process.

(b) Establishment of Regional Councils—membership.

(1) The number of members for each Regional Council shall be established by the Board, and shall be an odd number. A Regional Council member must be a resident of the region in which he or she is appointed and be knowledgeable about the region and subsistence uses of the public lands therein. The Board shall accept nominations and recommend to the Secretaries that representatives on the Regional Councils be appointed from those nominated by subsistence users. Appointments to the Regional Councils shall be made by the Secretaries.

(2) Regional Council members shall serve 3 year terms and may be reappointed. Initial members shall be appointed with staggered terms up to three years.

(3) The Chair of each Regional Council shall be elected by the applicable Regional Council, from its membership, for a one year term and may be reelected.

(c) Powers and Duties.

(1) The Regional Councils are authorized to:

(i) Hold public meetings related to subsistence uses of fish and wildlife within their respective regions, after the Chair of the Board or the designated Federal Coordinator has called the meeting and approved the meeting agenda;

(ii) Elect officers;

(iii) Review, evaluate, and make recommendations to the Board on proposals for regulations, policies, management plans, and other matters relating to the subsistence take of fish and wildlife under these regulations within the region;

(iv) Provide a forum for the expression of opinions and recommendations by persons interested in any matter related to the subsistence uses of fish and wildlife within the region;

(v) Encourage local and regional participation, pursuant to the provisions of these regulations in the decisionmaking process affecting the taking of fish and wildlife on the public lands within the region for subsistence uses;

(vi) Prepare and submit to the Board an annual report containing—

(A) An identification of current and anticipated subsistence uses of fish and wildlife populations within the region,

(B) An evaluation of current and anticipated subsistence needs for fish and wildlife populations from the public lands within the region,

(C) A recommended strategy for the management of fish and wildlife populations within the region to accommodate such subsistence uses and needs related to the public lands, and

(D) Recommendations concerning policies, standards, guidelines, and regulations to implement the strategy;

(vii) Appoint members to each Subsistence Resource Commission (Commission) within their region in accordance with the requirements of section 808 of ANILCA;

(viii) Make recommendations on determinations of customary and traditional use of subsistence resources;

(ix) Make recommendations on determinations of rural status;

(x) Make recommendations regarding the allocation of subsistence uses among rural Alaska residents pursuant to § 17 of these regulations;

(xi) Develop proposals pertaining to the subsistence taking and use of fish and wildlife under these regulations, and review and evaluate such proposals submitted by other sources;

(xii) Provide recommendations on the establishment and membership of Federal Advisory Committees.

(2) The Regional Councils shall:

(i) Operate in conformance with the provisions of FACA and comply with rules of operation established by the Board;

(ii) Perform other duties specified by the Board.

§ 12 Local advisory committees.

(a) The Board shall establish such Federal Advisory Committees within each region as necessary at such time that it is determined, after notice and hearing and consultation with the State, that the existing State fish and game advisory committees do not adequately provide advice to, and assist, the particular Regional Council in carrying out its function as set forth in § 11 of these regulations.

(b) Federal Advisory Committees, if established by the Board, shall operate in conformance with the provisions of the FACA, and comply with rules of operation established by the Board.

§ 13 Board/agency relationships.

(a) General.

(1) The Board, in making decisions or recommendations, shall consider and ensure compliance with specific statutory requirements regarding the management of resources on public lands, recognizing that the management policies applicable to some public lands may entail methods of resource and habitat management and protection different from methods appropriate for other public lands.

(2) The Board shall promulgate regulations for subsistence taking of fish and wildlife on public lands. The Board is the final administrative authority on the promulgation of subparts C and D regulations relating to the subsistence taking of fish and wildlife on public lands.

(3) Nothing in these regulations shall enlarge or diminish the authority of any agency to promulgate regulations necessary for the proper management of public lands under their jurisdiction in accordance with ANILCA and other existing laws.

(b) Section 808 of ANILCA establishes National Park and Park Monument Subsistence Resource Commissions. Nothing in these regulations affects the duties or authorities of these commissions.

§ 14 Relationship to State procedures and regulations.

(a) State fish and game regulations apply to public lands and such laws are hereby adopted and made a part of these regulations to the extent they are not inconsistent with, or superseded by this Part.

(b) The Board may close public lands to hunting and fishing, or take actions to restrict the taking of fish and wildlife despite any State authorization for taking fish and wildlife on public lands. The Board may review and adopt State closures or restrictions which serve to

achieve the objectives of these regulations.

(c) The Board may enter into agreements with the State in order to coordinate respective management responsibilities.

(d) Petition for repeal of subsistence rules and regulations.

(1) The State of Alaska may petition the Secretaries for repeal of these subsistence rules and regulations when the State has enacted and implemented subsistence management and use laws which:

(i) Are consistent with sections 803, 804, and 805 of ANILCA; and

(ii) Provide for the subsistence definition, preference, and participation specified in sections 803, 804, and 805 of ANILCA.

(2) The State's petition shall:

(i) Be submitted to the Secretary of the Interior, U.S. Department of the Interior, Washington, DC 20240, and the Secretary of Agriculture, U.S. Department of Agriculture, Washington, DC 20240.

(ii) Include the entire text of applicable State legislation indicating compliance with sections 803, 804, and 805 of ANILCA; and

(iii) Set forth all data and arguments available to the State in support of legislative compliance with sections 803, 804, and 805 of ANILCA.

(3) If the Secretaries find that the State's petition contains adequate justification, a rulemaking proceeding for repeal of these regulations will be initiated. If the Secretaries find that the State's petition does not contain adequate justification, the petition will be denied by letter or other notice, with a statement of the ground for denial.

§ 15 Rural determination process.

(a) The Board shall determine if an area or community in Alaska is rural. In determining whether a specific area of Alaska is rural, the Board shall use the following guidelines.

(1) A community or area with a population of 2500 or less shall be deemed to be rural unless such a community or area possesses significant characteristics of a non-rural nature, or is considered to be socially and economically a part of an urbanized area.

(2) Communities or areas with populations above 2500 but not more than 7000 will be determined to be rural or non-rural.

(3) A community with a population of more than 7000 shall be presumed non-rural, unless such a community or area possesses significant characteristics of a rural nature.

(4) Population data from the most recent census conducted by the United States Bureau of Census as updated by the Alaska Department of Labor shall be utilized in this process.

(5) Community or area characteristics shall be considered in evaluating a community's rural or non-rural status. The characteristics may include, but are not limited to:

- (i) Use of fish and wildlife;
- (ii) Development and diversity of the economy;
- (iii) Community infrastructure;
- (iv) Transportation; and
- (v) Educational institutions.

(6) Communities or areas which are economically, socially and communally integrated shall be considered in the aggregate.

(b) The Board shall periodically review rural determinations. Rural determinations shall be reviewed on a ten year cycle, commencing with the publication of the year 2000 U.S. census. Rural determinations may be reviewed out-of-cycle in special circumstances. Once the Board makes a determination that a community has changed from rural to non-rural, a waiting period of five years shall be required before the non-rural determination becomes effective.

(c) Current determinations are listed at § _____.23.

§ _____.16 Customary and traditional use determination process.

(a) The Board shall determine which fish stocks and wildlife populations have been customarily and traditionally used for subsistence. These determinations shall identify the specific community's or area's use of specific fish stocks and wildlife populations. For areas managed by the National Park Service, where subsistence uses are allowed, the determinations may be made on an individual basis.

(b) A community or area shall generally exhibit the following factors, which exemplify customary and traditional use. The Board shall make customary and traditional use determinations based on application of the following factors:

- (1) A long-term consistent pattern of use, excluding interruptions beyond the control of the community or area;
- (2) A pattern of use recurring in specific seasons for many years;
- (3) A pattern of use consisting of methods and means of harvest which are characterized by efficiency and economy of effort and cost, conditioned by local characteristics;
- (4) The consistent harvest and use of fish or wildlife as related to past methods and means of taking; near, or

reasonably accessible from the community or area;

(5) A means of handling, preparing, preserving, and storing fish or wildlife which has been traditionally used by past generations, including consideration of alteration of past practices due to recent technological advances, where appropriate;

(6) A pattern of use which includes the handing down of knowledge of fishing and hunting skills, values and lore from generation to generation;

(7) A pattern of use in which the harvest is shared or distributed within a definable community of persons; and

(8) A pattern of use which relates to reliance upon a wide diversity of fish and wildlife resources of the area and which provides substantial cultural, economic, social, and nutritional elements to the community or area.

(c) The Board shall take into consideration the reports and recommendations of any appropriate Regional Council regarding customary and traditional uses of subsistence resources.

(d) Current determinations are listed in § _____.24.

§ _____.17 Determining priorities for subsistence uses among rural Alaska residents.

(a) Whenever it is necessary to restrict the subsistence taking of fish and wildlife on public lands in order to protect the continued viability of such populations, or to continue subsistence uses, the Board shall establish a priority among the rural Alaska residents after considering any recommendation submitted by an appropriate Regional Council.

(b) The priority shall be implemented through appropriate limitations based on the application of the following criteria to each area, community, or individual determined to have customary and traditional use, as necessary:

(1) Customary and direct dependence upon the populations as the mainstay of livelihood;

(2) Local residency; and

(3) The availability of alternative resources.

(c) If allocation on an area or community basis is not achievable, then the Board shall allocate subsistence opportunity on an individual basis through application of the above criteria.

(d) In addressing a situation where prioritized allocation becomes necessary, the Board shall solicit recommendations from the Regional Council in the area affected.

§ _____.18 Regulation adoption process.

(a) Proposals for changes to the Federal subsistence regulations in Subpart D shall be accepted by the Board according to a published schedule, but at least once a year. The Board shall develop and publish proposed regulations in the **Federal Register** and publish notice in local newspapers. Comments on the proposed regulations in the form of proposals shall be distributed for public review.

(1) Proposals shall be made available for at least a thirty (30) day review by the Regional Councils. Regional Councils shall forward their recommendations on proposals to the Board. Such proposals with recommendations may be submitted in the time period as specified by the Board or as a part of the Regional Council's annual report described in § _____.11, whichever is earlier.

(2) The Board shall publish notice throughout Alaska of the availability of proposals received.

(3) The public shall have at least thirty (30) days to review and comment on proposals.

(4) After the comment period the Board shall meet to receive public testimony and consider the proposals. The Board shall consider traditional use patterns when establishing harvest levels and seasons, and methods and means. The Board may choose not to follow any recommendation which the Board determines is not supported by substantial evidence, violates recognized principles of fish and wildlife conservation, or would be detrimental to the satisfaction of subsistence needs. If a recommendation approved by a Regional Council is not adopted by the Board, the Board shall set forth the factual basis and the reasons for their decision in writing to the Regional Council.

(5) Following consideration of the proposals the Board shall publish final regulations pertaining to subpart D in the **Federal Register**.

(b) Proposals for changes to subpart C shall be accepted by the Board according to a published schedule. The Board shall develop and publish proposed regulations in the **Federal Register** and publish notice in local newspapers. Comments on the proposed regulations in the form of proposals shall be distributed for public review.

(1) Public and governmental proposals shall be made available for a thirty (30) day review by the regional councils. Regional Councils shall forward their recommendations on proposals to the Board. Such proposals with recommendations may be submitted in

the time period as specified by the Board or as a part of the Regional Council's annual report described in § _____.11, whichever is earlier.

(2) The Board shall publish notice throughout Alaska of the availability of proposals received.

(3) The public shall have at least thirty (30) days to review and comment on proposals.

(4) After the comment period the Board shall meet to receive public testimony and consider the proposals. The Board may choose not to follow any recommendation which the Board determines is not supported by substantial evidence, violates recognized principles of fish and wildlife conservation, or would be detrimental to the satisfaction of subsistence needs. If a recommendation approved by a Regional Council is not adopted by the Board, the Board shall set forth the factual basis and the reasons for their decision in writing to the Regional Council.

(5) Following consideration of the proposals the Board shall publish final regulations pertaining to subpart C in the *Federal Register*. A Board decision to change a community's or area's status from rural to non-rural will not become effective until five years after the decision has been made.

(c) [Reserved.]

(d) Proposals for changes to subparts A and B shall be accepted by the Secretary of the Interior in accordance with 43 CFR 14.1-4.

§ _____.19 Closures and other special actions.

(a) The Board may make or direct restriction or closure of the taking of fish and wildlife for non-subsistence uses on public lands when necessary to assure the continued viability of particular fish or wildlife population, to continue subsistence uses of a fish or wildlife population, or for reasons of public safety or administration.

(b) After consulting with the State of Alaska, providing adequate notice to the public, and holding at least one public hearing in the vicinity of the affected communities, the Board may make or direct temporary closures to subsistence uses of a particular fish or wildlife population on public lands to assure the continued viability of a fish or wildlife population, or for reasons of public safety or administration. A temporary closure will not extend beyond the regulatory year in which it is promulgated.

(c) In an emergency situation, the Board may direct immediate closures related to subsistence or non-subsistence uses of fish and wildlife on

public lands, if necessary to assure the continued viability of a fish or wildlife population, or for public safety reasons. The Board shall publish notice and reasons justifying the emergency closure in the *Federal Register* and in newspapers of any area affected. The emergency closure shall be effective when directed by the Board, may not exceed 60 days, and may not be extended unless it is determined by the Board, after notice and hearing, that such closure should be extended.

(d) The Board may make or direct a temporary change to open or adjust the seasons or to increase the bag limits for subsistence uses of fish and wildlife populations on public lands. An affected rural resident, community, Regional Council, or administrative agency may request a temporary change in seasons or bag limits. Prior to implementing a temporary change, the Board shall consult with the State, shall comply with the provisions of 5 U.S.C. 551-559 (Administrative Procedures Act or APA), and shall provide adequate notice and opportunity to comment. The length of any temporary change shall be confined to the minimum time period or bag limit determined by the Board to be necessary to satisfy subsistence uses. In addition, a temporary change may be made only after the Board determines that the proposed temporary change will not interfere with the conservation of healthy fish and wildlife populations. The decision of the Board shall be the final administrative action.

(e) Regulations authorizing any individual agency to direct temporary or emergency closures on public lands managed by the agency remain unaffected by these regulations, which authorize the Board to make or direct restrictions, closures, or temporary changes for subsistence uses on public lands.

(f) Taking fish and wildlife in violation of a restriction, or temporary change authorized by the Board is prohibited.

§ _____.20 Request for reconsideration.

(a) Subparts C and D regulations published in the *Federal Register* are subject to requests for reconsideration.

(b) Any aggrieved person may file a request for reconsideration with the Board.

(c) To file a request for reconsideration, the requestor must notify the Board in writing within sixty (60) days of the effective date or date of publication of the notice, whichever is earliest, for which reconsideration is requested.

(d) It is the responsibility of a requestor to provide the Board with sufficient narrative evidence and

argument to show why the action by the Board should be reconsidered. The following information must be included in the request for reconsideration:

(1) The requestor's name, and mailing address;

(2) The action for which reconsideration is requested and the date of *Federal Register* publication of that action;

(3) A detailed statement of how the requestor is adversely affected by the action;

(4) A detailed statement of the facts of the dispute, the issues raised by the request, and specific references to any law, regulation, or policy that the requestor believes to be violated and the reason for such allegation;

(5) A statement of how the requestor would like the action changed.

(e) Upon receipt of a request for reconsideration, the Board shall transmit a copy of such request to any appropriate Regional Council for review and recommendation. The Board shall consider any Regional Council recommendations in making a final decision.

(f) If the request is justified, the Board shall implement a final decision on a request for reconsideration after compliance with 5 U.S.C. 551-559 (APA).

(g) If the request is denied, the decision of the Board represents the final administrative action.

§ _____.21 [Reserved.]

Subpart C—Board Determinations

§ _____.22 Subsistence resource regions.

(a) The following areas are hereby designated as subsistence resource regions:

- (1) Southeast Region,
- (2) Southcentral Region,
- (3) Kodiak/Aleutians Region,
- (4) Bristol Bay Region,
- (5) Yukon-Kuskokwim Delta Region,
- (6) Western Interior Region,
- (7) Seward Peninsula Region,
- (8) Northwest Arctic Region,
- (9) Eastern Interior Region,
- (10) North Slope Region.

(b) Maps delineating the boundaries of subsistence resource regions are available from the U.S. Fish and Wildlife Service.

§ _____.23 Rural determinations.

(a) All communities and areas have been determined by the Board to be rural in accordance with § _____.15 except the following:

- Adak;
- Fairbanks North Star Borough;

Homer area—including Homer, Anchor Point, Kachemak City, and Fritz Creek;

Juneau area—including Juneau, West Juneau and Douglas;

Kenai area—including Kenai, Soldotna, Sterling, Nikiski, Salamatof, Kalifornsky, Kasilof, and Clam Gulch;

Ketchikan area—including Ketchikan City, Clover Pass, North Tongass Highway, Ketchikan East, Mountain

Pass, Herring Cove, Saxman East, and parts of Pennekot Island;

Municipality of Anchorage; Seward area—including Seward and Moose Pass; Valdez; and, Wasilla area—including Palmer, Wasilla, Sutton, Big Lake, Houston, and Bodenbergt Butte.

(2) Maps delineating the boundaries of non-rural areas listed in paragraph (a)(1) are available from the U.S. Fish and Wildlife Service.

(b) [Reserved.]

§ _____.24 Customary and traditional use determinations.

(a) Rural Alaska residents of the listed communities and areas have been determined to have customary and traditional subsistence use of the specified species on Federal public lands in the specified areas:

(1) *Wildlife determinations.*

Area	Species	Determination
GMU 1.....	Brown bear.....	No determination, except no subsistence for residents of Wrangell, Klukwan, Haines and Skagway.
1(A).....	Deer.....	Rural residents of 1(A) and 2.
1(B).....	Deer.....	Rural residents of GMU 1(A), residents of 1(B), 2, and 3.
1(B).....	Goat.....	No determination, except no subsistence for residents of Petersburg, Kupreanof and outlying areas.
1(B) The Stikine River drainages only.....	Moose.....	Residents of Wrangell.
1(B) North of the LeConte Glacier and 1(C) Berner's Bay.....	Moose.....	No subsistence.
1(C).....	Black bear.....	Rural residents of GMU 1(C) and Haines, Gustavus, Klukwan, and Hoonah.
1(C).....	Deer.....	Rural residents of 1 (C) and (D), and residents of Hoonah and Gustavus.
1(C).....	Goat.....	Residents of Haines, Klukwan, and Hoonah.
1(D).....	Deer.....	No subsistence.
1(D).....	Moose.....	Residents of GMU 1(D).
GMU 2.....	Brown bear.....	No subsistence.
2.....	Deer.....	Rural residents of GMU 1(A) and residents of Units 2 and 3.
GMU 3.....	Deer.....	Residents of GMU 1(B) and 3, and residents of Port Alexander, Port Protection, Pt. Baker, and Meyer's Chuck.
GMU 4.....	Brown bear.....	Residents of GMU 4 and Kake.
4.....	Deer.....	Residents of GMU 4 and residents of Kake, Gustavus, Haines, Petersburg, Pt. Baker, Klukwan, Port Protection, and Wrangell.
GMU 5.....	Brown bear.....	Residents of Yakutat.
5.....	Deer.....	Residents of Yakutat.
5.....	Moose.....	Residents of GMU 5(A).
GMU 6.....	Brown bear.....	No subsistence.
6.....	Moose.....	No subsistence.
6.....	Wolf.....	Residents of Units 6, 9, 10 (Unimak Island only), 11-13 and 16-26.
6(A).....	Black bear.....	Residents of Yakutat.
6(B) and (C).....	Black bear.....	Residents of GMU 6 (B) and (C), except Cordova.
6(C) and (D).....	Goat.....	Rural residents of GMU 6 (C) and (D).
6(D).....	Black bear.....	Residents of Chenega Bay and Tatilek.
GMU 7.....	Brown bear.....	No subsistence.
7.....	Caribou.....	No subsistence.
7.....	Moose.....	No subsistence.
7.....	Sheep.....	No subsistence.
GMU 7, Brown Mountain hunt area.....	Goat.....	Residents of Port Graham and English Bay.
GMU 8.....	Brown bear.....	No subsistence.
8.....	Deer.....	Residents of GMU 8.
8.....	Elk.....	No subsistence.
8.....	Goat.....	No subsistence.
GMU 9.....	Wolf.....	Residents of Units 6, 9, 10 (Unimak Island only), 11-13 and 16-26.
9(A) and (B).....	Caribou.....	Residents of Units 9(B), 9(C) and 17.
9(A), (B), (C) and (E).....	Moose.....	Residents of GMU 9 (A), (B), (C) and (E).
9 (A), (C) and (D).....	Brown bear.....	No subsistence.
9(B).....	Brown bear.....	Residents of GMU 9(B).
9(C).....	Caribou.....	Residents of GMU 9(B), 9(C), 17 and residents of Egegik.
9(D).....	Bison.....	No subsistence.
9(D).....	Caribou.....	Residents of GMU 9(D), and residents of False Pass.
9(D).....	Moose.....	No subsistence.

Area	Species	Determination
9(E).....	Brown bear.....	Residents of Chignik Lake, Ivanof Bay and Perryville.
9(E).....	Caribou.....	Residents of Units 9 (B), (C), (E), 17, and residents of Nelson Lagoon and Sand Point.
GMU 10 Unimak Island.....	Caribou.....	Residents of False Pass.
10 Remainder.....	Caribou.....	No subsistence.
10.....	Wolf.....	Residents of Units 6, 9, 10 (Unimak Island only), 11-13 and 16-26.
GMU 11.....	Bison.....	No subsistence.
11.....	Brown Bear.....	No subsistence.
11.....	Caribou.....	Mentasta Herd—residents of Units 11, 12 (along Nabesna Road) and 13 (A)-(D).
11.....	Goat.....	No subsistence.
11.....	Sheep.....	Residents of Chisana, Chistochina, Chitina, Copper Center, Gakona, Glennallen, Gulkana, Kenny Lake, McCarthy Road, Mentasta Lake, Mentasta Pass (milepost 79-110) Nabesna Road, Siana, McCarthy/South Wrangell/South Park, Tazlina, and Tonsina. However no subsistence for Cantwell, east Glenn Highway (milepost 110-180) and to milepost 14 on the Lake Louise Road, Homestead North, Homestead South, Lake Louise, Paxson, Sourdough, Tanacross, Tok, and west Glenn Highway (milepost 78-110).
11.....	Moose.....	Residents of GMU 11, residents of GMU 12 (along Nabesna Road) and GMU 13 (A)-(D).
11.....	Wolf.....	Residents of Units 6, 9, 10 (Unimak Island only), 11-13 and 16-26.
11.....	Grouse (Spruce, Blue, Ruffed and Sharp-tailed).....	Residents of Units 11, 13, 15, 16, 20(D), 22, and 23.
11.....	Ptarmigan (Rock, Willow and White-tailed).....	Residents of Units 11, 13, 15, 16, 20(D), 22, and 23.
GMU 12.....	Brown bear.....	No subsistence.
12.....	Caribou-Nelchina Herd.....	Residents of Northway and Tetlin.
12.....	Caribou-40 Mile Herd.....	Residents of GMU 12, north of Wrangell Park Preserve and rural residents of GMU 20 (D) and (E).
12 South of a line from Noyes Mountain, southeast of the confluence of Tatschunda Creek to Nabesna River.	Moose.....	Residents of GMU 11 north of 62nd parallel and excluding BLM parcels of north and south Siana; and residents of GMU 12, 13 (A)-(D) and residents of Dot Lake.
12 East of the Nabesna River, south of the Winter Trail from Pickerel Lake to the Canadian Border.	Moose.....	Residents of GMU 12.
12 Remainder of GMU 12.....	Moose.....	Residents of GMU 12 and residents of Dot Lake and Mentasta Lake.
12.....	Wolf.....	Residents of Units 6, 9, 10 (Unimak Island only), 11-13 and 16-26.
12, Tok Management area.....	Sheep.....	No subsistence.
GMU 13.....	Brown bear.....	No subsistence.
13.....	Caribou-Nelchina Herd.....	Residents of Units 11, 13, and 12 (along Nabesna Road).
13 Tok and Delta Management Areas.....	Sheep.....	No subsistence.
13.....	Moose.....	Residents of GMU 13.
13.....	Wolf.....	Residents of Units 6, 9, 10 (Unimak Island only), 11-13 and 16-26.
13.....	Grouse (Spruce, Blue, Ruffed & Sharp-tailed).....	Residents of Units 11, 13, 15, 16, 20(D), 22 and 23.
13.....	Ptarmigan (Rock, Willow and White-tailed).....	Residents of Units 11, 13, 15, 16, 20(D), 22 and 23.
13(D).....	Goat.....	No subsistence.
13(D).....	Sheep.....	No subsistence.
13(E).....	Moose.....	No subsistence for residents of McKinley Village and the area along the Parks Highway between milepost 216 and 239 and households of the Denali National Park Headquarters.
GMU 14.....	Goat.....	No subsistence.
14.....	Moose.....	No subsistence.
14 (A) and (C).....	Sheep.....	No subsistence.
14 (B) and (C).....	Brown bear.....	No subsistence.
GMU 15.....	Brown Bear.....	No subsistence.
15.....	Grouse (Spruce, Blue, Ruffed and Sharp-tailed).....	Residents of Units 11, 13, 15, 16, 20(D), 22 and 23.
15.....	Ptarmigan (Rock, Willow and White-tailed).....	Residents of Units 11, 13, 15, 16, 20(D), 22 and 23.
15.....	Sheep.....	No subsistence.
15 (A) and (B).....	Moose.....	No subsistence.
15(C), that portion southwest of a line from Point Pogibshi to the point of land between Rocky Bay and Windy Bay.	Moose.....	Residents of English Bay and Port Graham.
15(C) The Port Dick and English Bay hunt areas.....	Moose.....	No subsistence.
15(C) The Seldovia hunt area.....	Goat.....	Residents of Port Graham and English Bay.
15(C) The Seldovia hunt area.....	Goat.....	Residents of Seldovia area.
GMU 16.....	Brown bear.....	No subsistence.

Area	Species	Determination
16	Sheep	No subsistence.
16	Wolf	Residents of Units 6, 9, 10 (Unimak Island only), 11-13 and 16-26.
16	Grouse (Spruce, Blue, Ruffed and Sharp-tailed)	Residents of Units 11, 13, 15, 16 20(D), 22, and 23.
16	Ptarmigan (Rock, Willow and White-tailed)	Residents of Units 11, 13, 15, 16, 20(D), 22, and 23.
16(A)	Moose	No subsistence.
16(B)	Moose	Residents of GMU 16(B).
GMU 17	Caribou	Residents of Units 9(B), 17 and residents of Lime Village and Stony River.
17	Wolf	Residents of Units 6, 9, 10 (Unimak Island only), 11-13 and 16-26.
17(A)	Brown bear	Residents of GMU 17, and residents of Goodnews Bay and Platinum.
17(A)	Moose	Residents of GMU 17 and residents of Goodnews Bay and Platinum.
17 (A) and (B) Those portions north and west of a line beginning from the GMU 18 boundary at the northwest end of Nenevok Lake, to the southern point of upper Togiak Lake, and northeast to the northern point of Nuyakuk Lake, northeast to the point where the GMU 17 boundary intersects the Shotgun Hills.	Brown bear	Residents of Kwethluk.
17 (A) and (B) Those portions north and west of a line beginning from the GMU 18 boundary at the northwest end of Nenevok Lake, to the southern point of upper Togiak Lake, and northeast to the northern point of Nuyakuk Lake, northeast to the point where the GMU 17 boundary intersects the Shotgun Hills.	Caribou	Residents of Kwethluk.
17 (A) and (B) Those portions north and west of a line beginning from the GMU 18 boundary at the northwest end of Nenevok Lake, to the southern point of upper Togiak Lake, and northeast to the northern point of Nuyakuk Lake, northeast to the point where the GMU 17 boundary intersects the Shotgun Hills.	Moose	Residents of Kwethluk.
17 (B) and (C)	Brown bear	Residents of GMU 17.
17 (B) and (C)	Moose	Residents of GMU 17, and residents of Nondalton, Levelock, Goodnews Bay and Platinum.
GMU 18	Brown bear	Residents of Akiachak, Akiak, Eek, Goodnews Bay, Kwethluk, Mt. Village, Napaskiak, Platinum, Quinhagak, St. Mary's, and Tuluksak.
18	Caribou (Kilbuck caribou herd only)	Interim determination by Federal Subsistence Board (12/18/91): Residents of Tuluksak, Akiak, Akiachak, Kwethluk, Bethel, Oscarville, Napaskiak, Napakiak, Kasigluk, Atmanthluak, Nunapitchuk, Tun-tutliak, Eek, Quinhagak, Goodnews Bay, Platinum, Togiak, and Twin Hills.
18	Caribou (except Kilbuck caribou herd)	Residents of Kwethluk.
18	Moose	Residents of GMU 18 and residents of Upper Kalskag.
18	Muskox	No subsistence.
18	Wolf	Residents of Units 6, 9, 10 (Unimak Island only), 11-13 and 16-26.
GMU 19	Wolf	Residents of Units 6, 9, 10 (Unimak Island only), 11-13 and 16-26.
19(A)	Brown bear	Residents of GMU 19(A), (D), and Residents of Tuluksak, Lower Kalskag and Kwethluk.
19 (A) and (B)	Moose	Residents of GMU 18 within Kuskokwim River drainage upstream from and including the Johnson River, and GMU 19.
19 (A) and (B)	Caribou	Residents of GMU 19 (A) and (B) and Kwethluk; and residents of GMU 18 in Kuskokwim Drainage and Kuskokwim Bay during the winter season.
19(B)	Brown bear	Residents of Kwethluk.
19(C)	Brown Bear	No subsistence.
19(C)	Caribou	Residents of GMU 19(C), and residents of Lime Village, McGrath, Nikolai, and Telida.
19(C)	Moose	Residents of GMU 19.
19 (C), (D)	Bison	No subsistence.
19(D)	Brown bear	Residents of GMU 19 (A) and (D), and residents of Tulusak and Lower Kalskag.
19(D)	Caribou	Residents of GMU 19(D), and residents of Lime Village, Sleetmute and Stony River.
19(D)	Moose	Residents of GMU 19 and residents of Lake Minchumina.
GMU 20	Wolf	Residents of Units 6, 9, 10 (Unimak Island only), 11-13 and 16-26.

Area	Species	Determination
20(A).....	Moose.....	Residents of Cantwell, Minto, and Nenana. No subsistence for residents of McKinley Village, the area along the Parks Highway between mileposts 216 and 239 and households of the Denali National Park Headquarters.
20 (A), (C) (Delta, Yanert, and 20(C) herds) and (D).....	Caribou.....	No determination, except no subsistence for residents of McKinley Village, the area along the Parks Highway between mileposts 216 and 239 and households of the Denali National Park Headquarters.
20(B).....	Moose.....	Minto Flats Management Area—residents of Minto and Nenana.
20(B).....	Moose.....	Remainder—rural residents of GMU 20(B), and residents of Nenana and Tanana.
20(C).....	Moose.....	Rural residents of GMU 20(C) (except that portion within Denali National Park and Preserve and that portion east of the Teklanika River), and residents of Cantwell, Manley, Minto, Nenana, the Parks Highway from milepost 300-309, Nikolai, Tanana and Telida. No subsistence for residents of McKinley Village, the area along the Parks Highway between mileposts 216 and 239 and households of the Denali National Park Headquarters.
20(D).....	Moose.....	Rural residents of GMU 20(D) and residents of Tanacross.
20(D).....	Bison.....	No subsistence.
20(D).....	Grouse, (Spruce, Blue, Ruffed and Sharp-tailed).....	Residents of Units 11, 13, 15, 16, 20(D), 22 and 23.
20(D).....	Ptarmigan (Rock, Willow and White-tailed).....	Residents of Units 11, 13, 15, 16, 20(D), 22 and 23.
20 Tok and Delta Management Areas.....	Sheep.....	No subsistence.
20(D) and 20(E).....	Caribou 40-Mile Herd.....	Residents of GMU 12 north of Wrangell Park-Preserve, rural residents of 20(D) and residents of 20(E).
20(E).....	Brown bear.....	No subsistence.
20(F).....	Moose.....	Residents of GMU 20(F), Manley, Minto and Stevens Village.
GMU 21.....	Brown bear.....	Rural residents of GMU 21 and 23.
21.....	Wolf.....	Residents of Units 6, 9, 10 (Unimak Island only), 11-13 and 16-26.
21.....	Caribou, Western Arctic Caribou Herd only.....	Residents of GMU 21(D) west of the Koyukuk and Yukon Rivers, and residents of 22(A), (B), 23, 24, and 26(A).
21(A).....	Moose.....	Residents of GMU 21 (A), (E), Takotna, McGrath, Aniak and Crooked Creek.
21 (A) and (E).....	Caribou.....	Residents of GMU 21(A) and Aniak, Chuathbaluk, Crooked Creek, Grayling, Holy Cross, McGrath, Shageluk and Takotna.
21 (B) and (C).....	Moose.....	Residents of GMU 21 (B) and (C), residents of Tanana and Galena.
21(D).....	Moose.....	Residents of GMU 21(D), and residents of Huslia and Ruby.
21(E).....	Moose.....	Residents of GMU 21(E) and residents of Russian Mission.
GMU 22.....	Brown bear.....	Residents of GMU 22.
22.....	Caribou, Western Arctic Caribou Herd only.....	Residents of GMU 21(D) west of the Koyukuk and Yukon Rivers, and residents of Units 22(A), (B), 23, 24, and 26(A).
22.....	Moose.....	Residents of GMU 22.
22.....	Wolf.....	Residents of Units 6, 9, 10 (Unimak Island only), 11-13 and 16-26.
22.....	Grouse (Spruce, Blue, Ruffed and Sharp-tailed).....	Residents of Units 11, 13, 15, 16, 20(D), 22 and 23.
22.....	Ptarmigan (Rock, Willow and White-tailed).....	Residents of Units 11, 13, 15, 16, 20(D), 22, and 23.
22 (D), (E).....	Muskox.....	No subsistence.
GMU 23.....	Brown bear.....	Rural residents of Units 21 and 23.
23.....	Caribou Western Arctic Caribou Herd only.....	Residents of GMU 21(D) west of the Koyukuk and Yukon Rivers, and residents of GMU 22(A), (B), 23, 24, and 26(A).
23.....	Muskox.....	No subsistence.
23.....	Sheep.....	Residents of GMU 23 north of the Arctic Circle.
23.....	Moose.....	Residents of GMU 23.
23.....	Wolf.....	Residents of Units 6, 9, 10 (Unimak Island only), 11-13 and 16-26.
23.....	Grouse (Spruce, Blue, Ruffed and Sharp-tailed).....	Residents of Units 11, 13, 15, 16, 20(D), 22 and 23.
23.....	Ptarmigan (Rock, Willow and White-tailed).....	Residents of Units 11, 13, 15, 16, 20(D), 22 and 23.
GMU 24.....	Brown bear.....	Residents of GMU 24 and Wiseman, but not including any other residents of the Dalton Highway Corridor Management Area.

Area	Species	Determination
24	Sheep	Residents of GMU 24 residing north of the Arctic Circle and residents of Allakaket, Alatna and Anaktuvuk Pass.
24	Moose	Residents of GMU 24, and residents of Anaktuvuk Pass, Koyukuk, and Galena.
24	Wolf	Residents of Units 6, 9, 10 (Unimak Island only), 11-13 and 16-26.
GMU 25	Brown bear	No subsistence.
25	Wolf	Residents of Units 6, 9, 10 (Unimak Island only), 11-13 and 16-26.
25(A)	Sheep	Residents of Arctic Village, Chalkytsik, Fort Yukon, Kaktovik and Venetie.
25(A)	Moose	Residents of GMU 25(A) and residents of Venetie only.
25(B) and (C)	Sheep	No subsistence.
25(D) West	Moose	Residents of Beaver, Birch Creek and Stevens Village.
25(D) Remainder	Moose	Residents of "Remainder of GMU 25".
GMU 26	Brown bear	Residents of GMU 26 (except the Prudhoe Bay-Deadhorse Industrial Complex) and residents of Anaktuvuk Pass and Point Hope.
26	Caribou Western Arctic Caribou Herd only	Residents of GMU 21(D) west of the Koyukuk and Yukon Rivers, and residents of Units 22(A), (B), 23, 24, and 26(A).
26	Moose	Residents of GMU 26, (except the Prudhoe Bay-Deadhorse Industrial Complex), and residents of Point Hope and Anaktuvuk Pass.
26	Wolf	Residents of Units 6, 9, 10 (Unimak Island only), 11-13 and 16-26.
26(A)	Muskox	No subsistence.
26 (A) and (B)	Sheep	Residents of Anaktuvuk Pass, Kaktovik, Nuiqsut and Wiseman.
26(B)	Caribou Central Arctic Herd	Residents of Anaktuvuk Pass, Kaktovik, Nuiqsut and Wiseman.
26 (B) and (C)	Musk Oxen	Residents of Kaktovik.
26(C)	Sheep	Residents of Arctic Village, Chalkytsik, Fort Yukon, Kaktovik and Venetie.

(2) Fish and shellfish determinations.

Area	Species	Determination
Kotzebue-Northern Area-Northern District	All finfish	Residents of the Northern District, except for those domiciled in State of Alaska GMU 26-B.
Kotzebue-Northern Area-Kotzebue District	Salmon, shellfish, char	Residents of the Kotzebue District.
Norton Sound-Port Clarence Area	Salmon	Residents of the Norton Sound-Port Clarence Area.
Yukon Area	Salmon	Residents of the Yukon Area, including the community of Stebbins.
Yukon Area	Yukon River Fall chum salmon	Residents of the Yukon River drainage, including the communities of Stebbins, Scammon Bay, Hooper Bay, and Chevak.
Yukon Area	Freshwater fish species, including sheefish, whitefish, lamprey, burbot, sucker, grayling, pike, char, and blackfish.	Residents of the Yukon Area.
Kuskokwim Area	Salmon	Residents of the Kuskokwim Area, except those persons residing on the United States military installation located on Cape Newenham, Sparrevohn USAFB, and Tatalina USAFB.
Kuskokwim Area	Pacific cod	Residents of the communities of Chevak, Newtok, Tununak, Toksook Bay, Nightmute, Cheforak, Kipruk, Mekoryuk, Kwigillingok, Kongiganak, Eek, and Tuntutuliak.
Kuskokwim Area-Waters adjacent to the westernmost tip of the Naskonant Peninsula and the terminus of the Ishowik River and around Nunivak Island.	Herring and herring roe	Residents within 20 miles of the coast between the westernmost tip of the Naskonant Peninsula and the terminus of the Ishowik River and on Nunivak Island.
Bristol Bay Area-Nushagak District, including drainages flowing into the district.	Salmon	Residents of the Nushagak District and freshwater drainages flowing into the district.
Bristol Bay Area-Naknek-Kvichek District-Naknek River drainage.	Salmon	Residents of the Naknek and Kvichak River drainages.
Bristol Bay Area-Naknek-Kvichek District-Iliamna-Lake Clark drainage.	Salmon	Residents of the Iliamna-Lake Clark drainage.

Area	Species	Determination
Bristol Bay Area—Togiak District, including drainages flowing into the district.	Salmon and other freshwater finfish.....	Residents of the Togiak District, freshwater drainages flowing into the district, and the community of Manokotak.
Kodiak Area—except the Mainland District, all waters along the southside of the Alaska Peninsula bounded by the latitude of Cape Douglas (58°52' North latitude) mid-stream Shelikof Strait, and west of the longitude of the southern entrance of Kmuya Bay near Kilokak Rocks (57°11'22" North latitude, 156°20'30" W longitude.).	Salmon.....	Residents of the Kodiak Island Borough, except those residing on the Kodiak Coast Guard Base.
Kodiak Area—except the Semidi Island, the North Mainland, and the South Mainland Sections.	King crab.....	Residents of the Kodiak Island Borough except those residents on the Kodiak Coast Guard base.
Cook Inlet Area—Port Graham Sub-District.....	Dolly Varden.....	Residents of Port Graham and English Bay.
Cook Inlet Area—Port Graham Sub-District and Koyukotik Sub-District.	Salmon.....	Residents of Port Graham and English Bay.
Cook Inlet Area—Tyonek Sub-District.....	Salmon.....	Residents of the village of Tyonek.
Prince William Sound Area—South-Western District and Green Island.	Salmon.....	Residents of the Southwestern District which is mainland waters from the outer point on the north shore of Granite Bay to Cape Fairfield, and Knight Island, Chenega Island, Bainbridge Island, Evans Island, Elrington Island, Latouche Island and adjacent islands.
Prince William Sound Area—North of a line from Porcupine Point to Granite Point, and south of a line from Point Lowe to Tongue Point.	Salmon.....	Residents of the villages of Tatitlek and Ellamar.
Yakutat Area—Freshwater upstream from the terminus of streams and rivers of the Yakutat Area from the Doame River to the Tsiu River.	Salmon.....	Residents of the area east of Yakutat Bay, including the islands within Yakutat Bay, west of the Situk River drainage, and south of and including Knight Island.
Yakutat Area—Freshwater upstream from the terminus of streams and rivers of the Yakutat Area from the Doame River to Point Manby.	Dolly Varden char, steelhead trout, and smelt.....	Residents of the area east of Yakutat Bay, including the islands within Yakutat Bay, west of the Situk River drainage, and south of and including Knight Island.
South-Eastern Alaska Area—District 1—Section 1-E in waters of the Naha River and Roosevelt Lagoon.	Salmon and Dolly Varden char.....	Residents of the City of Saxman.
South-Eastern Alaska Area—District 1—Section 1-F in Boca de Quadra in waters of Sockeye Creek and Hugh Smith Lake within 500 yards of the terminus of Sockeye Creek.	Salmon and Dolly Varden char.....	Residents of the City of Saxman.
South-Eastern Alaska Area—District 2—North of the latitude of the northern-most tip of Chasina Point and west of a line from the northern-most tip of Chasina Point to the eastern-most tip of Grindall Island to the eastern-most tip of the Kasaan Peninsula.	Salmon and Dolly Varden char.....	Residents of the City of Kasaan and in the drainage of the southeastern shore of the Kasaan Peninsula west of 132° 20' W. long. and east of 132° 25' W. long.
South-Eastern Alaska Area—District 3—Section 3-A...	Salmon and Dolly Varden char.....	Residents of the townsite of Hydaburg.
South-Eastern Alaska Area—District 3—Section 3-B in waters east of a line from Point Ildefonso to Tranquil Point.	Salmon, Dolly Varden char, and steelhead trout.....	Residents of the City of Klawock and on Prince of Wales Island within the boundaries of the Klawock Heenya Corporation land holdings as they exist in January 1989, and those residents of the City of Craig and on Prince of Wales Island within the boundaries of the Shan Seet Corporation land holdings as they exist in January 1989.
South-Eastern Alaska Area—District 3—Section 3-C in waters of Sarkar Lakes.	Salmon, Dolly Varden char, and steelhead trout.....	Residents of the City of Klawock and on Prince of Wales Island within the boundaries of the Klawock Heenya Corporation land holdings as they exist in January 1989, and those residents of the City of Craig and on Prince of Wales Island within the boundaries of the Shan Seet Corporation land holdings as they exist in January 1989.
South-Eastern Alaska Area—District 5—North of a line from Point Barrie to Boulder Point.	Salmon and Dolly Varden char.....	Residents of the City of Kake and in Kupreanof Island drainages emptying into Keku Strait south of Point White and north of the Portage Bay boat harbor.
South-Eastern Alaska Area—District 9—Section 9-A...	Salmon and Dolly Varden char.....	Residents of the City of Kake and in Kupreanof Island drainages emptying into Keku Strait south of Point White and north of the Portage Bay boat harbor.
South-Eastern Alaska Area—District 9—Section 9-B north of the latitude of Swain Point.	Salmon and Dolly Varden char.....	Residents of the City of Kake and in Kupreanof Island drainages emptying into Keku Strait south of Point White and north of the Portage Bay boat harbor.
South-Eastern Alaska Area—District 10—West of a line from Pinta Point to False Point Pybus.	Salmon and Dolly Varden char.....	Residents of the City of Kake and in Kupreanof Island drainages emptying into Keku Strait south of Point White and north of the Portage Bay boat harbor.

Area	Species	Determination
South-Eastern Alaska Area—District 12—South of a line from Fishery Point to south Passage Point and north of the latitude of Point Caution.	Salmon and Dolly Varden char.....	Residents of the City of Angoon and along the western shore of Admiralty Island north of the latitude of Sand Island, south of the latitude of Thayer Creek, and west of 134° 30' W. long., including Killisnoo Island.
South-Eastern Alaska Area—District 13—Section 13-A south of the latitude of Cape Edward.	Sockeye salmon.....	Residents of the City and Borough of Sitka in drainages which empty into Section 13-B north of the latitude of Dorothy Narrows.
South-Eastern Alaska Area—District 13—Section 13-B north of the latitude of Redfish Cape.	Sockeye salmon.....	Residents of the City and Borough of Sitka in drainages which empty into Section 13-B north of the latitude of Dorothy Narrows.
South-Eastern Alaska Area—District 13—Section 13-C.	Sockeye salmon.....	Residents of the City and Borough of Sitka in drainages which empty into Section 13-B north of the latitude of Dorothy Narrows.
South-Eastern Alaska Area—District 13—Section 13-C east of the longitude of Point Elizabeth.	Salmon and Dolly Varden char.....	Residents of the City of Angoon and along the western shore of Admiralty Island north of the latitude of Sand Island, south of the latitude of Thayer Creek, and west of 134° 30' W. long., including Killisnoo Island.
South-Eastern Alaska Area—District 14—Section 14-B and 14-C.	Salmon, smelt and Dolly Varden char.....	Residents of the City of Hoonah and in Chichagof Island drainages on the eastern shore of Port Frederick from Gartina Creek to Point Sophia.
South-Eastern Alaska Area—District 15—Chilkat and Chilkoot Rivers.	Salmon and smelt.....	Residents west of the Haines highway between Mile 20 and Mile 24 and east of the Chilkat River, but not elsewhere in Klukwan; and, those residents of other areas of the city and borough of Haines, excluding residents in the drainage of Excursion Inlet.

For the reasons set out in the preamble, chapter I, subchapter H of title 50 and chapter II of title 36 of the Code of Federal Regulations are amended as follows:

TITLE 36—PARKS, FORESTS AND PUBLIC PROPERTY

CHAPTER II—FOREST SERVICE, DEPARTMENT OF AGRICULTURE

1. The authority citation for part 242 continues to read as follows:

Authority: 16 U.S.C. 3, 472, 551, 668dd, 3101–3126; 18 U.S.C. 3551–3586; 43 U.S.C. 1733.

2. Subparts A, B, and C of part 242 of title 36 are revised as set forth at the end of the common rule.

PART 242—SUBSISTENCE MANAGEMENT REGULATIONS FOR PUBLIC LANDS IN ALASKA

Subpart A—General Provisions

Sec.

- 242.1 Purpose.
- 242.2 Authority.
- 242.3 Applicability and scope.
- 242.4 Definitions.
- 242.5 Eligibility for subsistence use.
- 242.6 Licenses, permits, harvest tickets, tags, and reports.
- 242.7 Restriction on use.
- 242.8 Penalties.
- 242.9 Information collection requirements.

Subpart B—Program Structure

- 242.10 Federal Subsistence Board.
- 242.11 Regional advisory councils.
- 242.12 Local advisory committees.
- 242.13 Board/agency relationships.

- 242.14 Relationship to State procedures and regulations.
- 242.15 Rural determination process.
- 242.16 Customary and traditional use determination process.
- 242.17 Determining priorities for subsistence uses among rural Alaska residents.
- 242.18 Regulation adoption process.
- 242.19 Closures and other special actions.
- 242.20 Request for reconsideration.
- 242.21 [Reserved.]

Subpart C—Board Determinations

- 242.22 Subsistence resource regions.
- 242.23 Rural determinations.
- 242.24 Customary and traditional use determinations.

TITLE 50—WILDLIFE AND FISHERIES

CHAPTER I—UNITED STATES FISH AND WILDLIFE SERVICE, DEPARTMENT OF THE INTERIOR

1. The authority citation for part 100 is revised to read as follows:

Authority: 5 U.S.C. Appendix 1–15, 16 U.S.C. 3, 472, 551, 668dd; 3101–3126; 18 U.S.C. 3551–3586; 43 U.S.C. 1733.

2. Subparts A, B, and C of part 100 of title 50 are revised as set forth at the end of the common rule.

PART 100—SUBSISTENCE MANAGEMENT REGULATIONS FOR PUBLIC LANDS IN ALASKA

Subpart A—General Provisions

Sec.

- 100.1 Purpose.
- 100.2 Authority.
- 100.3 Applicability and scope.
- 100.4 Definitions.

Sec.

- 100.5 Eligibility for subsistence use.
- 100.6 Licenses, permits, harvest tickets, tags, and reports.
- 100.7 Restriction on use.
- 100.8 Penalties.
- 100.9 Information collection requirements.

Subpart B—Program Structure

- 100.10 Federal Subsistence Board.
- 100.11 Regional advisory councils.
- 100.12 Local advisory committees.
- 100.13 Board/agency relationships.
- 100.14 Relationship to State procedures and regulations.
- 100.15 Rural determination process.
- 100.16 Customary and traditional use determination process.
- 100.17 Determining priorities for subsistence uses among rural Alaska residents.
- 100.18 Regulation adoption process.
- 100.19 Closures and other special actions.
- 100.20 Request for reconsideration.
- 100.21 [Reserved.]

Subpart C—Board Determinations

- 100.22 Subsistence resource regions.
- 100.23 Rural determinations.
- 100.24 Customary and traditional use determinations.

Dated: May 8, 1992.

Richard N. Smith,

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